

PACKAGE LEAFLET: INFORMATION FOR THE USER

SOLIQUA™

100 units/mL + 33 micrograms/mL solution for injection in a pre-filled pen

This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
If you have any further questions, ask your doctor or pharmacist or nurse.
This medicine has been prescribed for you only. Do not pass it on to others.

What is in this leaflet:

- 1. What Soliqua is and what it is used for
2. What you need to know before you use Soliqua
3. How to use Soliqua
4. Possible side effects
5. How to store Soliqua
6. Contents of the pack and other information

1. WHAT SOLIQUA IS AND WHAT IT IS USED FOR

Soliqua is an injectable diabetes medicine that contains two active substances:

- insulin glargine: a long acting type of insulin which helps control blood sugar (glucose) throughout the day
Lixisenatide: a "GLP-1 analogue" that helps the body produce its own additional insulin in response to increases in blood sugar, and slows the absorption of sugar from foods.

Soliqua is used to treat adults with type 2 diabetes, to help control blood sugar levels when they are too high. It is given with metformin, when other medicines are not enough on their own to control your blood sugar levels.

If you use another anti-diabetic medicine, discuss with your doctor whether you should stop using that medicine when starting Soliqua.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SOLIQUA

Contraindications: Do not use Soliqua:
if you are allergic to insulin glargine or lixisenatide or to any of the other ingredients of this medicine (listed in section 6).

Appropriate precautions for use: special warnings: Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Soliqua if:

- you have type 1 diabetes, as Soliqua is used for type 2 diabetes and this medicine will not be right for you.
you have diabetic ketoacidosis (a complication of diabetes that occurs when the body is unable to use glucose because there is not enough insulin) since this medicine will not be right for you.
you have a severe stomach or gut problem such as a disease of the muscles of the stomach called "gastroparesis" which results in delayed stomach emptying. Since Soliqua may cause stomach side effects, the medicine has not been studied in patients with severe stomach or gut problems. Please see the information regarding medicines that should not stay too long in your stomach in the section "Other medicines and Soliqua".
you have severe kidney disease or you are on dialysis as the use of this medicine will not be recommended

Follow closely your doctor's instructions for dose, monitoring (blood and urine tests), diet and physical activity (physical work and exercise) and injection technique.

Be especially aware of the following:

- Too low blood sugar (hypoglycaemia). If your blood sugar is too low, follow the guidance for hypoglycaemia (see information in the box at the end of this leaflet).
Too high blood sugar (hyperglycaemia). If your blood sugar is too high, follow the guidance for hyperglycaemia (see information in the box at the end of this leaflet).
Ensure that you use the right medicine. You must always check the label before each injection to avoid mix-ups between Soliqua and other insulins.
If you have poor eyesight, please see section 3.

While using this medicine be aware of the following and talk to doctor, pharmacist or nurse before using Soliqua:

- severe pain in your stomach area (abdomen) that will not go away. This could be a sign of inflamed pancreas (acute pancreatitis).
loss of fluids from your body (dehydration) e.g. in case of vomiting and diarrhoea. It is important to avoid dehydration by drinking plenty of fluids, especially during the first weeks of treatment with Soliqua.

Travel

Talk to your doctor before travelling. You may need to talk about:

- If your medicine is available in the country you are visiting.
How to arrange the supply of your medicine, needles and other items.
How to correctly store your medicine while travelling.
The time you eat meals and use your medicine.
The possible effects of changing to different time zones.
Any health risks in the countries you will visit.
What you should do in an emergency if you feel unwell or become ill.

Children and adolescents

There is no experience with Soliqua in children and adolescents aged less than 18 years, therefore, the use of Soliqua is not recommended in this age group.

Other medicines and Soliqua

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

Some medicines can change your blood sugar level. This may mean your Soliqua dose has to change. So, before taking a medicine ask your doctor if it will affect your blood sugar and what action, if any, you need to take. You also need to be careful when you stop taking a medicine.

The effect of some medicines you swallow might be affected by Soliqua. Some medicines such as antibiotics, oral contraceptives, statins (medicines like atorvastatin to lower cholesterol) acid resistant tablets or capsules that should not stay too long in your stomach may need to be taken at least one hour before or four hours after your Soliqua injection.

Your blood sugar level may fall (hypoglycaemia) if you take:

- Any other medicine to treat diabetes.
Disopyramide, for some heart problems.
Fluoxetine, for depression.
Sulfonamide antibiotics, to treat infections.
Fibrates, for lowering high levels of blood fats.
Monoamine oxidase inhibitors (MAOIs), for depression or Parkinson's disease.
Angiotensin converting enzyme (ACE) inhibitors, for heart problems or high blood pressure.
Medicines to relieve pain and lower fever, such as paracetamol, propoxyphene and salicylates (such as acetylsalicylic acid).
Pentamidine, for some parasite infections. This may cause too low blood sugar which is sometimes followed by too high blood sugar.

Your blood sugar level may rise (hyperglycaemia) if you take:

- Corticosteroids such as cortisone and prednisolone, for inflammation.
Danazol, for endometriosis.
Diazoxide, for high blood pressure.
Protease inhibitors, for HIV.
Diuretics, for high blood pressure or fluid retention.
Glucagon, for very low blood sugar.
Isoniazid, for tuberculosis.
Somatropin, a growth hormone.
Thyroid hormones, for thyroid gland problems.
Oestrogens and progestogens, such as in the contraceptive pill for birth control or use of oestrogens for bone loss (osteoporosis).
Clozapine, olanzapine and phenothiazine derivatives, for mental health problems.
Sympathomimetic medicines such as epinephrine (adrenaline), salbutamol and terbutaline, for asthma.

Your blood sugar level may either rise or fall if you take:

- Beta-blockers or clonidine, for high blood pressure.
Lithium salts, for mental health problems.

Medicine that may reduce warning signs of low blood sugar

Beta-blockers and some other medicines (such as clonidine, guanethidine, reserpine, for high blood pressure) may make it harder to recognise warning signs of your low blood sugar levels (hypoglycaemia). They can even hide or stop the first signs that your blood sugar is too low.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before using this medicine.

Warfarin or other anticoagulants

Tell your doctor if you are taking warfarin or other anticoagulants (medicines used to prevent clotting of the blood) as you might need to have more frequent blood tests (called "International Normalised Ratio" or INR test) to check your blood clotting.

Soliqua with alcohol

Your blood sugar level may either rise or fall if you drink alcohol. You should check your blood sugar level more often.

Pregnancy and breast-feeding

Soliqua should not be used during pregnancy. It is not known if Soliqua harms your unborn child. Soliqua should not be used if breast-feeding. It is not known if Soliqua passes into your milk. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Having too low or too high blood sugar (see information in the box at the end of this leaflet) can affect your ability to drive and use tools or machines. Your concentration may be affected. This could be dangerous to yourself and others.

Ask your doctor whether you can drive if:

- Your blood sugar is often too low.
You find it hard to recognise when your blood sugar is too low.

Important information about some of the ingredients of Soliqua

This medicine contains less than 1 mmol (23 mg) sodium per dose. This means it is essentially "sodium-free". This medicine contains metacresol which may cause allergic reactions.

3. HOW TO USE SOLIQUA

Always use this medicine exactly as your doctor has told you. Your doctor may tell you to use a different dose of Soliqua compared to your previous insulin dose. Check with your doctor, pharmacist or nurse if you are not sure.

Based on your lifestyle, your blood sugar tests and your previous insulin use, your doctor will tell you:
How much Soliqua you need each day and at what time.
When to check your blood sugar level and if you need to carry out urine tests.
When you may need a higher or lower dose.

Your doctor may tell you to use Soliqua with other medicines for high blood sugar.

How much to use

Soliqua 100 units/mL + 33 micrograms/mL pre-filled SoloStar pen:
This pen provides a dose of 30 to 60 dose steps in one injection, in steps of 1 dose step.
Each dose step you dial contains 1 unit of insulin glargine and 0.33 micrograms of lixisenatide.

Your dose of Soliqua is administered as 'dose steps'. The dose window on the pen shows the number of dose steps.

Do not inject a dose lower than 30 dose steps. If a dose lower than 30 dose steps is needed, use the Soliqua 100 units/mL + 50 micrograms pre-filled pen (Soliqua 10-40) pen.

Do not inject a dose greater than 60 dose steps.

Many factors may affect your blood sugar level. You should know what they are so that you can take the right action if your blood sugar level changes and help stop it becoming too high or too low. See the box at the end of this leaflet for more information.

Use in elderly patients (65 years and over)

If you are 65 years or older, talk to your doctor as you may need a lower dose.

If you have kidney or liver problems

If you have kidney or liver problems, talk to your doctor as you may need a lower dose.

When to inject Soliqua

Use Soliqua once a day, within 1 hour before a meal. Preferably inject Soliqua before the same meal every day, when you have chosen the most convenient one.

Before injecting Soliqua

- Always follow the "Instructions for Use" that come with this package leaflet.
If you do not follow all of these instructions, you may get too much or too little of Soliqua.

To avoid mistakes, always check the medicine pack and label on the pen before each injection to make sure you have the correct pen, especially if you inject more than one medicine. Ask your doctor or pharmacist if you are not sure.

Other important information about using the pre-filled pens

- Always use a new needle for each injection. The re-use of needles increases the risk of blocked needles which may cause under- or over-dosing. Dispose of the needle safely after each use.
To prevent infection being passed from one person to another, pens should never be used for more than one person, even when the needle is changed. Only use needles that are compatible for use with Soliqua pen (see "Instructions for Use").

- A safety test must be performed before each injection.
If you think your pen is damaged, do not use it. Get a new one. Do not try to repair the pen.
Throw away the used needle in a sharps container, or as told by your pharmacist or local authority.

How to inject

- Soliqua is injected under the skin (subcutaneous use or "SC").
Inject it into the front of your thighs, upper arms or the front of your waist (abdomen).
Change the place within the area you inject each day. This will reduce the risk of developing dents or lumps at the site (for more information, see "Other side effects" in section 4).

Do not use Soliqua:

- in a vein. This will change the way it works and may cause your blood sugar to become too low,
if there are particles in Soliqua. The solution should be clear, colourless and water-like.

Never use a syringe to remove the solution from the pen to avoid dosing errors and potential overdose.

If the pen is damaged, has not been stored correctly, if you are not sure that it is working properly or you notice that your blood sugar control is unexpectedly getting worse:

- throw the pen away and use a new one.
talk to your doctor, pharmacist or nurse if you think you have a problem with your pen.

If you use more Soliqua than you should

If you have injected too much of this medicine, your blood sugar level may become too low (hypoglycaemia). Check your blood sugar and eat more food to prevent your blood sugar getting too low (hypoglycaemia). If your blood sugar gets too low, see the advice in the box at the end of this leaflet.

If you forget to use Soliqua

If you have missed a dose of Soliqua or if you have not injected enough insulin, your blood sugar level may become too high (hyperglycaemia).

- When needed, Soliqua can be injected before the next meal.
Do not inject a double dose to make up for a forgotten dose.
Do not take two injections per day.
Check your blood sugar and then inject your next dose at the usual time.
For information on the treatment of hyperglycaemia, see the box at the end of this leaflet.

If you stop using Soliqua

Do not stop using this medicine without talking to your doctor. If you do, it could lead to very high blood sugar (hyperglycaemia) and a build-up of acid in the blood (ketoacidosis).

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice signs of your blood sugar being too low (hypoglycaemia), take action to increase your blood sugar level straight away (see the box at the end of this leaflet).

Hypoglycaemia can be very serious and is very common with medicine containing insulin (may affect more than 1 in 10 people). Low blood sugar means that there is not enough sugar in your blood.

If your blood sugar falls too low, you may pass out (become unconscious). If blood sugar remains very low for too long it may cause brain damage and may be life-threatening. For more information, see the box at the end of this leaflet.

Other side effects

Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

- Common: may affect up to 1 in 10 people
Feeling dizzy
Feeling sick (Nausea)
Vomiting
Diarrhoea

Uncommon: may affect up to 1 in 100 people

- Cold, runny nose, sore throat
Hives (urticaria)
Headache
Indigestion (dyspepsia)
Stomach ache
Tiredness

Changes where the injection is given: If you inject Soliqua too often in the same place, you may develop dents at the site, caused by a loss of fat under the skin (lipoatrophy) or you may develop lumps, caused by a build-up of fat under the skin (lipohypertrophy). The medicine may not work very well. Change the injection site with each injection to help prevent these changes.

Skin and allergic reactions at the injection site: The signs may include reddening, unusually intense pain when injecting, itching, hives, swelling or inflammation. This can spread

around the injection site. Most minor reactions to insulins usually disappear in a few days to a few weeks.

Reporting of side effects: If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SOLIQUA

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN

Do not use this medicine after the expiry date which is stated on the carton and on the label of the pen after "EXP". The expiry date refers to the last day of that month.

Before first use

Store in a refrigerator (2°C - 8°C). Do not freeze or place next to the freezer compartment or a freezer pack. Keep the pen in the outer carton in order to protect from light.

After first use or if carried as a spare

The pen may be stored for a maximum of 14 days out of the refrigerator, but below 30°C. Discard the pen after this time period.

Do not return the pen to a refrigerator and do not freeze. Store the pen away from direct heat or direct light. Always keep the cap on the pen when you are not using it in order to protect it from light. Do not leave the pen in a car on an exceptionally warm or cold day. Do not store the pen with the needle attached.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer used. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Soliqua contains: The active substances are insulin glargine and lixisenatide. Each pen contains 3 mL of solution for injection, equivalent to 300 units insulin glargine and 100 micrograms lixisenatide.

Each mL contains 100 units and 33 mcg lixisenatide. Each dose step of Soliqua contains 1 unit of insulin glargine and 0.33 mcg of lixisenatide. The other ingredients are: 85% glycerol, methionine, metacresol, zinc chloride, concentrated hydrochloric acid, and sodium hydroxide (for pH adjustment) and water for injections. See also section 2 "What you need to know before you use Soliqua" for information on sodium and metacresol.

What Soliqua looks like and contents of the pack: Soliqua is a clear and colourless solution filled in a glass cartridge inserted in a SoloStar pre-filled pen. Each Soliqua pen contains 3 mL of solution.

Packs of 3 and 5 pre-filled pens. Not all pack sizes may be marketed in your country.

Needles are not included in the pack.

Marketing Authorisation Holder:

sanofi-aventis groupe
54, rue La Boétie
75008 Paris
France

Manufacturer: Sanofi-Aventis Deutschland GmbH
Industriepark Höchst
65926 Frankfurt am Main
Germany

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Handwritten Arabic text: نسخة مطابقة للشروط المرفقة بال EPP
قرار السيد النائب الخاص بالمشرف على
ادارة تسجيل المستحضرات الحيوية
نشرة معدلة تاريخ: 09/12/19
Signature: [Handwritten Signature]

HYPERGLYCAEMIA AND HYPOGLYCAEMIA

If you use insulin, you should always carry the following things with you:

- Foods containing sugar, such as dextrose or a sugary drink (at least 20 grams).
Information so that others know you have diabetes.

Hyperglycaemia (high blood sugar levels)

If your blood sugar is too high (hyperglycaemia), you may not have injected enough insulin.

Reasons why hyperglycaemia may happen:

- You have not injected your Soliqua or not injected enough.
Your medicine has become less effective - for example because it was not stored properly.
Your pen does not work properly.
You are doing less exercise than usual.
You are under stress - such as emotional distress or excitement.
You have an injury, infection or fever or have had an operation.
You are taking or have taken certain other medicines (see section 2, "Other medicines and Soliqua").

Warning signs of hyperglycaemia

Thirst, increased need to urinate, tiredness, dry skin, reddening of the face, loss of appetite, low blood pressure, fast heartbeat, and glucose and urine test showing ketone bodies. Stomach pain, fast and deep breathing, feeling sleepy or passing out (becoming unconscious) may be signs of a serious condition (ketoacidosis) resulting from lack of insulin.

What to do if you experience hyperglycaemia

Test your blood sugar level and, if it is high and as agreed with your doctor or nurse, test your urine for ketones as soon as you notice any of the above signs. Contact your doctor straight away if you have severe hyperglycaemia or ketoacidosis. This must always be treated by a doctor, normally in a hospital.

Hypoglycaemia (low blood sugar levels)

If your blood sugar level falls too much you may pass out (become unconscious). Serious hypoglycaemia may cause a heart attack or brain damage and may be life-threatening. You should learn to recognise the signs when your blood sugar is falling - so you can take action to stop it getting worse.

Reasons why hypoglycaemia may happen:

- You inject too much Soliqua.
You miss meals or delay them.
You do not eat enough, or eat food containing less carbohydrates than normal - artificial sweeteners are not carbohydrates.
You drink alcohol - especially when you have not eaten much.
You lose carbohydrates from being sick (vomiting) or diarrhoea.
You are doing more exercise than usual or a different type of physical activity.
You are recovering from an injury, operation or other stress.
You are recovering from an illness or from fever.
You are taking or have stopped taking certain other medicines (see section 2, "Other medicines and Soliqua").

Hypoglycaemia is also more likely to happen if:

- You have just started Soliqua treatment - if low blood sugar occurs, it may be more likely to happen in the morning.
Your blood sugar levels are almost normal or are unstable.
You change the area where you inject Soliqua. For example from the thigh to the upper arm.
You have severe kidney or liver disease, or some other disease such as hypothyroidism.

Warning signs of hypoglycaemia

The first signs may be in your body generally. Examples of signs that your blood sugar level is falling too much or too fast include: sweating, clammy skin, feeling anxious, fast or irregular heartbeat, high blood pressure and palpitations. These signs often develop before the signs of a low sugar level in the brain.

Other signs include: headaches, feeling very hungry, feeling sick (nausea) or being sick (vomiting), feeling tired, sleepy, restless, sleeping problems, aggressive behaviour, difficulty concentrating, slow reactions, depression, feeling confused, difficulty speaking (sometimes total loss of speech), changes in your sight, trembling, being unable to move (paralysis), tingling in the hands or arms, feeling numb and tingling often around the mouth, feeling dizzy, loss of self-control, being unable to look after yourself, fits, passing out.

When the signs of hypoglycaemia may be less clear: The first warning signs of hypoglycaemia may change, be weaker or missing altogether, if:

- You are elderly.
You have had diabetes for a long time.
You have a certain type of nerve damage (called "diabetic autonomic neuropathy").
You have recently had too low blood sugar (for example the day before).
Your low blood sugar occurs on slowly.
Your low blood sugar is always around "normal" or your diabetes control has greatly improved recently.
You have recently changed from animal insulin to a manufactured insulin, like there is in Soliqua.
You are taking or have taken certain other medicines (see section 2, "Other medicines and Soliqua").

In such cases, you may develop severe hypoglycaemia (and even pass out) before you know what is happening. Be familiar with your warning signs. If necessary, you might need to test your blood sugar more often. This can help to spot mild hypoglycaemic episodes. If you find it difficult to recognise your warning signs, you should avoid situations (such as driving a car) in which you or others would be put at risk by hypoglycaemia.

What to do if you experience hypoglycaemia?

- Do not inject Soliqua. Take about 15 to 20 grams of sugar straight away - such as glucose, sugar cubes or a sugary drink. Drinks or foods that contain artificial sweeteners (such as diet drinks) do not help treat low blood sugar.
You might then need to eat something (such as bread or pasta) that will raise your blood sugar over a longer time, especially if your next meal is not due. Ask your doctor or nurse if you are not sure which foods you should eat.
With Soliqua, it may take longer to recover from low blood sugar because it contains a long-acting insulin (insulin glargine).

Table with 2 columns: SAP-Air / Plant PM code, Sprachvariante / Country code, Version, Zeilenabstand / Line spacing, Datum / Date.

Table with 2 columns: Abmessungen / Dimensions, Schriftgröße / Font size, Zeilenabstand / Line spacing, Seite / Page.

Table with 2 columns: Druckbare Farben / Printing colours, Black.

Table with 2 columns: Technische Information / Technical information, Kontur / Outline.

Soliqua 100 units/mL + 33 micrograms/mL solution for injection in a pre-filled pen (30-60). INSTRUCTIONS FOR USE

Read the Package Leaflet and these Instructions for Use first

Soliqua (30-60) pen contains insulin glargine and lisinsinamide. The combination of medicinal products in this pen is for the daily injection of 30 to 60 dose steps Soliqua.

- Never re-use needles. If you do, you might not get your full dose (under dosing) or get too much (overdosing) as the needle could block.
- Never use a syringe to remove medicine product from your pen. If you do, you may not get the correct amount of medicine.

Keep these Instructions For Use leaflet for future reference.

Important information

- Never share your pen – it is only for you
- Never use your pen if it is damaged or if you are not sure that it is working properly.
- Always perform a safety test. (See STEP 3).
- Always carry a spare pen and spare needles in case they get lost or stop working.
- Always check the label of the pen before use to make sure you have the correct pen.

Learn to inject:

- Talk with your healthcare provider about how to inject, before using your pen.
- Ask for help if you have problems handling the pen, for example if you have problems with your sight.
- Read all of these instructions before using your pen. If you do not follow all of these instructions, you may get too much or too little medicine.

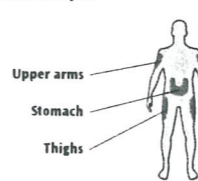
Need help?

If you have any questions about Soliqua, the pen or about diabetes, ask your doctor, pharmacist or nurse or call the local sanofi-aventis number.

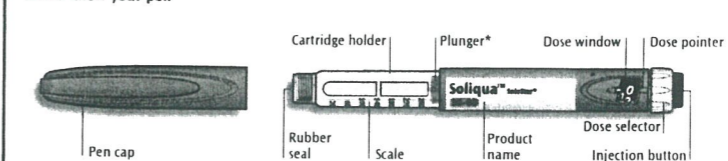
Extra items you will need:

- a new sterile needle (see STEP 2).
- a sharps container for used needles and pens. (See **Throwing your pen away**).

Places to inject



Get to know your pen



*You will not see the plunger until you have injected a few doses

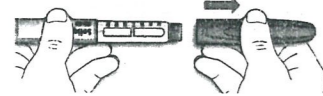
STEP 1: Check your pen

Take a new pen out of the refrigerator at least 1 hour before you inject. Injecting cold medicine is more painful.

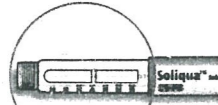
- A. Check the name and expiry date on the label of your pen.**
- Make sure you have the correct medicine. This pen is olive coloured with a brown injection button.
 - Do not use this pen if you need a daily dose less than 30 dose steps or if you need more than 60 dose steps. Discuss with your doctor which pen is suitable for your needs.
 - Do not use your pen after the expiry date.



- B. Pull off the pen cap.**



- C. Check that the medicine is clear.**
- Do not use the pen if the medicine looks cloudy, coloured or contains particles.



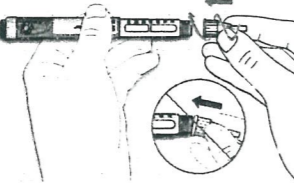
STEP 2: Attach a new needle

- Do not reuse needles. Always use a new sterile needle for each injection. This helps stop blocked needles, contamination, and infection.
- Always use needles that are compatible for use with Soliqua pen.

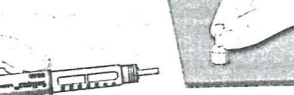
- A. Take a new needle and peel off the protective seal.**



- B. Keep the needle straight and screw it onto the pen until fixed. Do not over-tighten.**



- C. Pull off the outer needle cap. Keep this for later.**



- D. Pull off the inner needle cap and throw away.**



Handling needles

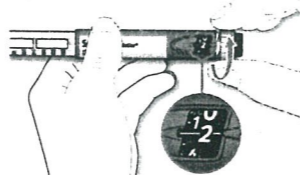
- Take care when handling needles to prevent needle injury and cross-infection.

STEP 3: Do a safety test

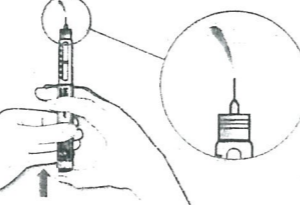
Always do a safety test before each injection to:

- Check your pen and the needle to make sure they are working properly
- Make sure that you get the correct dose.

- A. Select 2 dose steps by turning the dose selector until the dose pointer is at the 2 mark.**



- B. Press the injection button all the way in.**
- When medicine comes out of the needle tip, your pen is working correctly, the dose selector will be reset to "0".



If no liquid appears:

- You may need to repeat this step up to 3 times before seeing medicine.
- If no medicine comes out after the third time, the needle may be blocked. If this happens:
 - change the needle (see STEP 2 and STEP 3).
 - then repeat the safety test (STEP 3).
- Do not use your pen if there is still no medicine coming out of the needle tip. Use a new pen.
- Do not use a syringe to remove medicine from your pen.

If you see air bubbles

- You may see air bubbles in the medicine. This is normal, they will not harm you.

STEP 4: Select the dose

- Only use this pen to inject single daily doses from 30 to 60 dose steps.
- Do not select a dose or press the injection button without a needle attached. This may damage your pen.

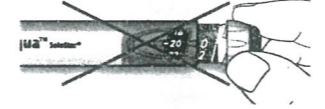
- A. Make sure a needle is attached and the dose is set to "0".**



- B. Turn the dose selector until the dose pointer lines up with your dose.**
- If you turn past your dose, you can turn back down.
 - If there are not enough dose steps left in your pen for your dose, the dose selector will stop at the number of dose steps left.
 - If you cannot select your full prescribed dose, use a new pen or inject the remaining dose steps and use a new pen to complete your dose. Only in this case, it is okay to inject a partial dose of less than 30 dose steps. Always use another Soliqua (30-60) pen to complete your dose and no other pen.

How to read the dose window

- Do not use the pen if your single daily dose is less than 30 dose steps, shown as white numbers on a black background.



Units of medicine in your pen

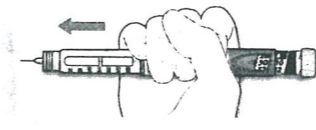
- Your pen contains a total of 300 dose steps. You can select your dose in steps of 1 dose step.
- Do not use this pen if you need a single daily dose that is less than 30 dose steps, or more than 60 dose steps.
- Each pen contains more than 1 dose.

STEP 5: Inject the dose

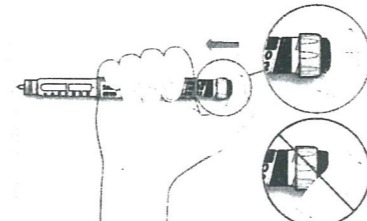
- If you find it hard to press the injection button in, do not force it as this may break your pen:
- Change the needle (see STEP 6 "Remove the needle" and STEP 2 "Attach a new needle") then do a safety test (see STEP 3).
- If you still find it hard to press in, get a new pen.
- Do not use a syringe to remove medicine from your pen.

- A. Choose a place to inject as shown in the picture above.**

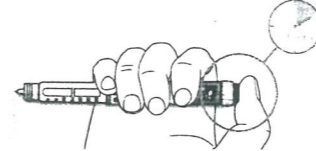
- B. Push the needle into your skin as shown by your healthcare provider.**
- Do not touch the injection button yet.



- C. Place your thumb on the injection button. Then press all the way in and hold.**
- Do not press at an angle. Your thumb could block the dose selector from turning.



- D. Keep the injection button held in and when you see "0" in the dose window, slowly count to 10.**
- This will make sure you get your full dose.

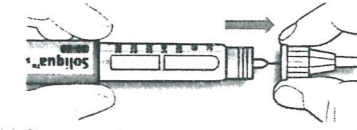


- E. After holding and slowly counting to 10, release the injection button. Then remove the needle from your skin.**

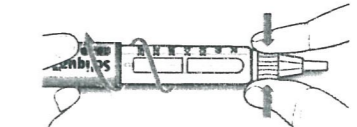
STEP 6: Remove the needle

- Take care when handling needles to prevent needle injury and cross-infection.
- Do not put the inner needle cap back on.

- A. Grip the widest part of the outer needle cap. Keep the needle straight and guide it into the outer needle cap back. Then push firmly on.**
- The needle can puncture the cap if it is recapped at an angle.



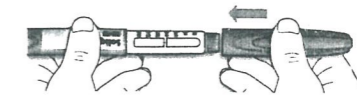
- B. Grip and squeeze the widest part of the outer needle cap. Turn your pen several times with your other hand to remove the needle.**
- Try again if the needle does not come off the first time.



- C. Throw away the used needle in a puncture resistant container (see "Throwing your pen away" at the end of this "Instructions for Use").**



- D. Put your pen cap back on.**
- Do not put the pen back in the refrigerator.



How to store your pen

Before first use

- Keep new pens in the refrigerator between 2°C to 8°C.
- Do not freeze.

After first use

- Keep your pen at room temperature, below 30°C.
- Do not put your pen back in the refrigerator.
- Do not store your pen with the needle attached.
- Store the pen with your pen cap on.
- Only use your pen for up to 14 days after its first use.

How to care for your pen

Handle your pen with care

- If you think that your pen may be damaged, do not try to fix it. Use a new one.

Protect your pen from dust and dirt

- You can clean the outside of your pen by wiping it with a damp cloth (water only). Do not soak, wash or lubricate the pen. This may damage it.

Throwing your pen away

- Remove the needle before throwing your pen away.
- Throw away your used pen as instructed by your pharmacist or local authority.

| | | | | | |
|--------------------------------|---------------|-------------------------------------|-------------|--|---|
| Legende / Legend | | Druckbare Farben / Printing colours | | Technische Information / Technical information | |
| SAP-Nr. / Plant PM code: | 536614A | Abmessungen / Dimensions: | 59 x 420 mm | Black | ■ |
| Sprachvariante / Country code: | 056 | Schriftgröße / Font size: | 9 Pt | Yellow | ■ |
| Version: | 4 | Zellenabstand / Line spacing: | 10 Pt | Cyan | ■ |
| Datum / Date: | 19.04.2017 UK | Seite / Page: | 4/6 | Magenta | ■ |
| | | | | Kontur / Outline | ■ |

وزارة الصحة والسكان
 الادارة المركزية لشؤون الصيدلة
 ادارة تسجيل المستحضرات الصيدلانية
 ملاحظات مملوكة تاريخها 11/05/2018
 د. مكي ابراهيم

<MAT>541637



GTIN 03582910080961

SN
 Lot/Batch :
 Fab/Orig :
 Exp:

Pour un usage individuel uniquement.
 Toujours utiliser une aiguille neuve.

Chaque stylo prérempli contient 300 unités d'insuline glargine et 100 microgrammes de lixisénatide dans une solution de 3 ml.

Chaque ml contient 100 unités d'insuline glargine et 33 microgrammes de lixisénatide.

Chaque étape de dosage contient 1 unité d'insuline glargine et 0,33 mcg de lixisénatide.

Excipients : glycérol 85%, méthionine, métacrésol, chlorure de zinc, acide chlorhydrique, hydroxyde de sodium (pour ajustement de pH), eau pour préparations injectables.

Lire la notice avant utilisation.

TENIR HORS DE LA VUE ET DE LA PORTEE DES ENFANTS.

N'utiliser que des solutions claires et incolores.

Avant première utilisation

A conserver au réfrigérateur (entre 2°C et 8°C). Ne pas congeler ou placer près du compartiment congélateur ou d'une poche de congélation.

Conservé le stylo prérempli dans l'emballage extérieur à l'abri de la lumière.

Après première utilisation

A conserver à une température ne dépassant pas 30°C. Ne pas congeler.

Ne pas conserver le stylo avec l'aiguille fixée dessus.

Conservé le stylo à l'abri de la chaleur directe ou de la lumière directe. Remettez le capuchon sur le stylo après chaque injection afin de le protéger de la lumière.

For single patient use only.
 Always use a new needle.

Each pen contains 300 units of insulin glargine and 100 micrograms of lixisenatide in 3 ml solution.

Each ml contains 100 units of insulin glargine and 33 micrograms of lixisenatide.

Each dose step contains 1 unit of insulin glargine and 0,33 mcg of lixisenatide.

Excipients: glycerol 85%, methionine, metacresol, zinc chloride, hydrochloric acid, sodium hydroxide (for pH adjustment), water for injections.

Read the package leaflet before use.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Use only clear, colourless solution.

Not in-use pens

Store in a refrigerator (2°C - 8°C). Do not freeze or place next to the freezer compartment or a freezer pack.

Keep the pen in the outer carton in order to protect from light.

In-use pens

Store below 30°C. Do not refrigerate. Do not freeze.

Store the pen away from direct heat or direct light. The pen cap must be put back on the pen after each injection in order to protect from light.



3 582910 080961

لاستعمال لدى مريض واحد فقط.
 استعمال إبر جديدة دائما.

يحتوي كل قلم على 300 وحدة من الأنسولين غلارجين وعلى 100 ميكروغرام من الليكسيناتيد في محلول من 3 مل.

يحتوي كل مل على 100 وحدة من الأنسولين غلارجين وعلى 33 ميكروغرام من الليكسيناتيد.

تحتوي كل خطوة معلومة جرعة على وحدة واحدة من الأنسولين غلارجين وعلى 0,33 ميكروغرام من الليكسيناتيد.

المكونات: غليسرول 85%، ميثيونين، ميتاكريسول، كلوريد الزنك، حمض الهيدروكلوريك، هيدروكسيد الصوديوم (لضبط الرقم الهيدروجيني)، ماء للحقن.

اقرأ النشرة قبل الاستخدام.

إيداع الدواء بعيداً عن نحر الأطفال ومشترايين.

استعمل فقط المحلول السائل والصفي اللون.

الأقلام غير المستخدمة

إيداع الأقلام في البراد (بين درجتين مئويتين و 8 درجات مئوية). لا تجمدها ولا تضعها قرب النارجة أو حمرة التجميد.

إيداع القلم في العبوة الخارجية لحمايته من الضوء.

الأقلام قيد الاستخدام

إيداعها في حرارة ما دون 30 درجة مئوية.

لا تضعها في البراد، لا تجمدها.

إيداع القلم بعيداً عن الحرارة المباشرة أو الضوء المباشر.

يجب إيداع وضع الغطاء على القلم بعد كل سلسة حقن لحمايته من الضوء.

RESERVED TO PROSES PRESCRIBERS
 USE THE DOSE AS PRESCRIBED
 Uniquement sur ordonnance
 Prescription only medicine
 دواء إيداع فقط على وصفة طبية



Date of opening /
 تاريخ الصلاحية /
 Après première utilisation :
 à utiliser dans les 14 jours.
 After first use:
 use within 14 days.
 Fab/Orig :
 Sanofi-Aventis Deutschland GmbH
 54, rue La Boétie
 75008 Paris
 France
 Sanofi-Aventis Gruppe
 6592 Frankfurt am Main
 Germany

SOLIQUA™ SoloStar®

100 unités/ml + 33 microgrammes/ml
 100 units/ml + 33 micrograms/ml
 سوليكا™ سولوستار® 100 وحدة/مل + 33 ميكروغرام/مل

Solution injectable en stylo prérempli
 Solution for injection in a pre-filled pen
 محلول للحقن في قلم مملئ مسبقاً

insuline glargine + lixisénatide
 insulin glargine + lixisenatide
 أنسولين غلارجين + ليكسيناتيد

30-60 étapes de dosage
 dose steps
 60-30 خطوة لجرعة الجرعة

(خطوة واحدة لجرعة الجرعة)
 = 1 unité d'insuline glargine + 0,33 microgrammes de lixisénatide
 = 1 unit of insulin glargine + 0,33 micrograms of lixisenatide
 = وحدة واحدة من الأنسولين غلارجين + 0,33 ميكروغرام من الليكسيناتيد

A injecter exclusivement à l'aide de ce stylo.
 Use only in this pen.
 للاستعمال حصراً في هذا القلم

Voie sous-cutanée
 Subcutaneous use
 للحقن تحت الجلد



Ouvrir ici / Open here / افتح هنا

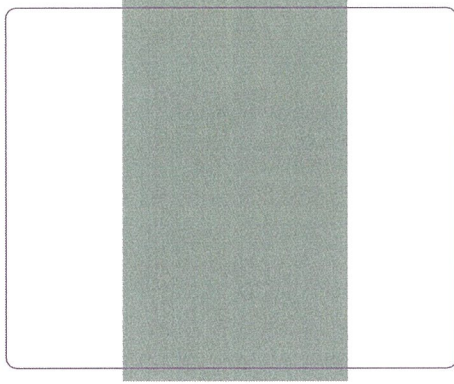
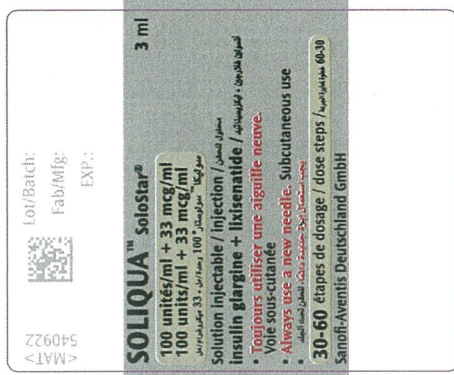
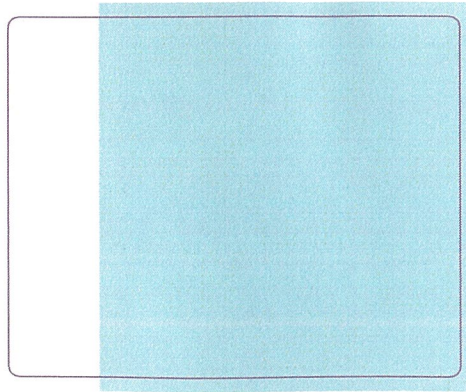
- يتم الالتزام بطباعة هاتفي:
- رقم التسجيل وتاريخ الإنتاج وتاريخ انتهاء الصلاحية (يوم - شهر - سنة).
 - رقم التسجيل بوزارة الصحة كما ورد في إخطار التسجيل.
 - سعر البيع للجمهور كما ورد في إخطار التسجيل.
 - اسم المستورد في مصر وعنوانه.

| Legende / Legend | Druckbare Farben / Printing colours | Technische Information / Technical information |
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| Sprachvariante / Country code: 056 | Pantone 1225 C | Stanze / Die |
| Version: 1 | Pantone 186 C | |
| Datum / Date: 03.07.2018 PE | Pantone 151 C | |
| Abmessungen / Dimensions: 172 x 85 x 25 mm | Pantone 451 C | |
| Kleinste verwendete Schriftgröße / Minimum point size of text: 6.5 pt | Pantone 168 C | |
| Seite / Page: 1/1 | | |

الإتمام بطباعة رقم التشغيل وتاريخ الإنتاج وتاريخ انتهاء الصلاحية (يوم - شهر - سنة).

وزارة الصحة والسكان
الإدارة المركزية لشؤون الصيدلة
الإدارة العامة للمستشفيات الحكومية
تاريخ: ٢٠١٤ / ٥ / ٢٤

د/مايكو ابراهيم



Legende / Legend

SAP-Nr. / Plant PM code: 540922
Sprachvariante / Country code: 056
Version: 1
Datum / Date: 26.02.2018 AR
Abmessungen / Dimensions: 62,1 x 49,5 mm
Kleinste verwendete Schriftgröße / Minimum point size of text: 6 pt
Seite / Page: 1/1

Druckbare Farben / Printing colours

Pantone Black C
Pantone 451 C
Pantone 186 C
Weiss / white

Technische Information / Technical information

Kontur / Contour
Lumilack / Lumiphore coating

PACKAGE LEAFLET: INFORMATION FOR THE USER

SOLIQUA™

100 units/ml + 50 micrograms/ml solution for injection in a pre-filled pen Insulin glargine + lixisenatide



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Soliqua is and what it is used for
2. What you need to know before you use Soliqua
3. How to use Soliqua
4. Possible side effects
5. How to store Soliqua
6. Contents of the pack and other information

1. WHAT SOLIQUA IS AND WHAT IT IS USED FOR

Soliqua is an injectable diabetes medicine that contains two active substances:
- insulin glargine: a long-acting type of insulin which helps control blood sugar (glucose) throughout the day.
- lixisenatide: a "GLP-1 analogue" that helps the body produce its own additional insulin in response to increases in blood sugar, and slows the absorption of sugar from foods

Soliqua is used to treat adults with type 2 diabetes, to help control blood sugar levels when they are too high. It is given, with metformin, when other medicines are not enough on their own to control your blood sugar levels. These other medicines may include oral anti-diabetics (such as metformin, sulfonylurea medicines) or insulin.

If you use another anti diabetic medicine, discuss with your doctor whether you should stop using that medicine when starting Soliqua.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SOLIQUA

Contraindications:

- Do not use Soliqua:
- if you are allergic to insulin glargine or lixisenatide or to any of the other ingredients of this medicine (listed in section 6).

Appropriate precautions for use: special warnings: Warnings and precautions

- Talk to your doctor, pharmacist or nurse before using Soliqua if:
- you have type 1 diabetes, as Soliqua is used for type 2 diabetes and this medicine will not be right for you.
- you have diabetic ketoacidosis (a complication of diabetes that occurs when the body is unable to use glucose because there is not enough insulin) since this medicine will not be right for you.
- you have a severe stomach or gut problem such as a disease of the muscles of the stomach called "gastroparesis" which results in delayed stomach emptying. Since Soliqua may cause stomach side effects, the medicine has not been studied in patients with severe stomach or gut problems. Please see the information regarding medicines that should not stay too long in your stomach in the section "Other medicines and Soliqua"
- you have severe kidney disease or you are on dialysis as the use of this medicine will not be recommended.

Follow closely your doctor's instructions for dose, monitoring (blood and urine tests), diet and physical activity (physical work and exercise) and injection technique.

Be especially aware of the following:

- Too low blood sugar (hypoglycaemia). If your blood sugar is too low, follow the guidance for hypoglycaemia (see information in the box at the end of this leaflet).
- Too high blood sugar (hyperglycaemia). If your blood sugar is too high, follow the guidance for hyperglycaemia (see information in the box at the end of this leaflet).
- Ensure that you use the right medicine. You must always check the label before each injection to avoid mix-ups between Soliqua and other insulins.
- If you have poor eyesight, please see section 3.

While using this medicine be aware of the following and talk to your doctor, pharmacist or nurse before using Soliqua:
- severe pain in your stomach area (abdomen) that will not go away. This could be a sign of inflamed pancreas (acute pancreatitis).
- loss of fluids from your body (dehydration) e.g. in case of vomiting and diarrhoea. It is important to avoid dehydration by drinking plenty of fluids, especially during the first weeks of treatment with Soliqua.

Travel

- Talk to your doctor before travelling. You may need to talk about:
- If your medicine is available in the country you are visiting.
- How to arrange the supply of your medicine, needles and other items.
- How to correctly store your medicine while travelling.
- The time you eat meals and use your medicine.
- The possible effects of changing to different time zones.
- Any health risks in the countries you will visit.
- What you should do in an emergency if you feel unwell or become ill.

Children and adolescents
There is no experience with Soliqua in children and adolescents aged less than 18 years; therefore, the use of Soliqua is not recommended in this age group.

Other medicines and Soliqua
Tell your doctor, pharmacist or nurse if you are using, have recently used, or might use any other medicines.

Some medicines can change your blood sugar level. This may mean your Soliqua dose has to change. So, before taking a medicine ask your doctor if it will affect your blood sugar and what action, if any, you need to take. You also need to be careful when you stop taking a medicine.

The effect of some medicines you swallow might be affected by Soliqua. Some medicines such as antibiotics, oral contraceptives, statins (medicines like atorvastatin to lower cholesterol), acid-resistant tablets or capsules that should not stay too long in your stomach may need to be taken at least one hour before or four hours after your Soliqua injection.

Your blood sugar level may fall (hypoglycaemia) if you take:

- Any other medicine to treat diabetes.
- Disopyramide, for some heart problems.
- Fluoxetine, for depression.
- Sulfonamide antibiotics, to treat infections.
- Fibrates, for lowering high levels of blood fats.
- Monoamine oxidase inhibitors (MAOIs), for depression or Parkinson's disease.
- Angiotensin converting enzyme (ACE) inhibitors, for heart problems or high blood pressure.
- Medicines to relieve pain and lower fever, such as paracetamol, propoxyphene and salicylates (such as acetylsalicylic acid).
- Pentamidine, for some parasite infections. This may cause too low blood sugar which is sometimes followed by too high blood sugar.

Your blood sugar level may rise (hyperglycaemia) if you take:

- Corticosteroids such as cortisone and prednisolone, for inflammation.
- Danazol, for endometriosis.
- Diazoxide, for high blood pressure.
- Diuretics, for high blood pressure or fluid retention.
- Glucagon, for very low blood sugar.
- Isoniazid, for tuberculosis.
- Somatropin, a growth hormone.
- Thyroid hormones, for thyroid gland problems.
- Gestrogens and progestogens, such as in the contraceptive pill for birth control or use of oestrogens for bone loss (osteoporosis).
- Clozapine, olanzapine and phenothiazine derivatives, for mental health problems.
- Sympathomimetic medicines such as epinephrine (adrenaline), salbutamol and terbutaline, for asthma.

Your blood sugar level may either rise or fall if you take:

- Beta-blockers or clonidine, for high blood pressure.
- Lithium salts, for mental health problems.

Medicine that may reduce warning signs of low blood sugar

Beta-blockers and some other medicines (such as clonidine, guanethidine, reserpine - for high blood pressure) may make it harder to recognise warning signs of your low blood sugar levels (hypoglycaemia). They can even hide or stop the first signs that your blood sugar is too low.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before using this medicine.

Warfarin or other anticoagulants
Tell your doctor if you are taking warfarin or other anticoagulants (medicines used to prevent clotting of the blood) as you might need to have more frequent blood tests (called 'International Normalised Ratio' or INR test) to check your blood clotting.

Soliqua with alcohol
Your blood sugar level may either rise or fall if you drink alcohol. You should check your blood sugar level more often.

Pregnancy and breast-feeding
Soliqua should not be used during pregnancy. It is not known if Soliqua harms your unborn child. Soliqua should not be used if breast-feeding. It is not known if Soliqua passes into your milk. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Having too low or too high blood sugar (see information in the box at the end of this leaflet) can affect your ability to drive and use tools or machines. Your concentration may be affected. This could be dangerous to yourself and others.

Ask your doctor whether you can drive if:
- Your blood sugar is often too low.
- You find it hard to recognise when your blood sugar is too low.

Important information about some of the ingredients of Soliqua
This medicine contains less than 1 mmol (23 mg) sodium per dose. This means it is essentially 'sodium-free'. This medicine contains metacresol which may cause allergic reactions.

3. HOW TO USE SOLIQUA

Always use this medicine exactly as your doctor has told you. Your doctor may tell you to use a different dose of Soliqua compared to your previous insulin dose. Check with your doctor, pharmacist or nurse if you are not sure.

Based on your lifestyle, your blood sugar tests and your previous insulin use, your doctor will tell you:
- How much Soliqua you need each day and at what time.
- When to check your blood sugar level and if you need to carry out urine tests.
- When you may need a higher or lower dose.

Your doctor may tell you to use Soliqua with other medicines for high blood sugar.

How much to use
Soliqua 100 units/ml + 50 micrograms/ml pre-filled pen:

- This pen provides a dose of 10 to 40 dose steps in one injection, in steps of 1 dose step.
- Each dose step you dial contains 1 unit of insulin glargine and 0.5 micrograms of lixisenatide.

Your dose of Soliqua is administered as 'dose steps'. The dose window on the pen shows the number of dose steps.

Do not inject a dose lower than 10 dose steps. Do not inject a dose higher than 40 dose steps. If a dose greater than 40 dose steps is needed, your doctor will prescribe a different strength. For dose steps from 30-60 units, Soliqua 100 units/ml + 33 micrograms/ml solution for injection in a pre-filled pen is available.

Many factors may affect your blood sugar level. You should know what they are so that you can take the right action if your blood sugar level changes and help stop it becoming too high or too low. See the box at the end of this leaflet for more information.

Use in elderly patients (65 years and older)
If you are 65 years or older, talk to your doctor as you may need a lower dose.

If you have kidney or liver problems
If you have kidney or liver problems, talk to your doctor as you may need a lower dose.

When to inject Soliqua
Use Soliqua once a day, within 1 hour before a meal. Preferably inject Soliqua before the same meal every day, when you have chosen the most convenient one.

Before injecting Soliqua
- Always follow the "Instructions for Use" that come with this package leaflet.
- If you do not follow all of these instructions, you may get too much or too little of Soliqua.

To avoid mistakes, always check the medicine pack and label on the pen before each injection to make sure you have the correct pen, especially if you inject more than one medicine. Ask your doctor or pharmacist if you are not sure.

Other important information about using the pre-filled pens

- Always use a new needle for each injection. The re-use of needles increases the risk of blocked needles which may cause under- or over-dosing. Dispose of the needle safely after each use.
- To prevent infection being passed from one person to another, pens should never be used for more than one person, even when the needle is changed.
- Only use needles that are compatible with Soliqua pen (see "Instructions for Use").

- A safety test must be performed before each injection.
- If you think your pen is damaged, do not use it. Get a new one. Do not try to repair the pen.
- Throw away the used needle in a sharps container, or as told by your pharmacist or local authority.

How to inject
- Soliqua is injected under the skin (subcutaneous use or "SC").
- Inject into the front of your thighs, upper arms or the front of your waist (abdomen).

- Change the place within the area you inject each day. This will reduce the risk of developing dents or lumps at the site (for more information, see "Other side effects" in section 4).

Do not use Soliqua:
- in a vein. This will change the way it works and may cause your blood sugar to become too low.
- if there are particles in Soliqua. The solution should be clear, colourless and water-like.

Never use a syringe to remove the solution from the pen to avoid dosing errors and potential overdose.

If the pen is damaged, has not been stored correctly, if you are not sure that it is working properly or you notice that your blood sugar control is unexpectedly getting worse:
- throw the pen away and use a new one.
- talk to your doctor, pharmacist or nurse if you think you have a problem with your pen.

If you use more Soliqua than you should
If you have injected too much of this medicine, your blood sugar level may become too low (hypoglycaemia). Check your blood sugar and eat more food to prevent your blood sugar getting too low (hypoglycaemia). If your blood sugar gets too low, see the advice in the box at the end of this leaflet.

If you forget to use Soliqua
If you have missed a dose of Soliqua or if you have not injected enough insulin, your blood sugar level may become too high (hyperglycaemia). When needed, Soliqua can be injected before the next meal.
- Do not inject a double dose to make up for a forgotten dose.
- Do not use two injections per day.
- Check your blood sugar and then inject your next dose at the usual time.
- For information on the treatment of hyperglycaemia, see the box at the end of this leaflet.

If you stop using Soliqua
Do not stop using this medicine without talking to your doctor. If you do, it could lead to very high blood sugar (hyperglycaemia) and a build-up of acid in the blood (ketoacidosis).

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice signs of your blood sugar being too low (hypoglycaemia), take action to increase your blood sugar level straightaway (see the box at the end of this leaflet).

Hypoglycaemia can be very serious and is very common with medicines containing insulin (may affect more than 1 in 10 people).

Low blood sugar means that there is not enough sugar in your blood. If your blood sugar falls too low, you may pass out (become unconscious). If blood sugar remains very low for too long it may cause brain damage and may be life-threatening. For more information, see the box at the end of this leaflet.

Other side effects
Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

- Common: may affect up to 1 in 10 people
- Feeling dizzy
- Feeling sick (Nausea)
- Vomiting
- Diarrhoea

- Uncommon: may affect up to 1 in 100 people
- Cold, runny nose, sore throat
- Hives (urticaria)
- Headache
- Indigestion (dyspepsia)
- Stomachache
- Tiredness
- Changes where the injection is given: If you inject Soliqua too often in the same place, you may develop dents at the site, caused by a loss of fat under the skin (lipatrophy) or you may develop lumps, caused by a build-up of fat under the skin (lipohypertrophy). The medicine may not work very well. Change the injection site with each injection to help prevent these changes.
- Skin and allergic reactions at the injection site: The signs may include reddening, unusually intense pain when injecting, itching, hives, swelling or inflammation. This can spread

around the injection site. Most minor reactions to insulins usually disappear in a few days to a few weeks.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SOLIQUA

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN

Do not use this medicine after the expiry date which is stated on the carton and on the label of the pen after "EXP". The expiry date refers to the last day of that month.

Before first use
Store in a refrigerator (2°C - 8°C). Do not freeze or place next to the freezer compartment or a freezer pack. Keep the pen in the outer carton in order to protect from light.

After first use or if carried as a spare
The pen may be stored for a maximum of 14 days out of the refrigerator, but below 30°C. Discard the pen after this period. Do not return the pen to a refrigerator and do not freeze. Store the pen away from direct heat or direct light. Always keep the cap on the pen when you are not using it in order to protect it from light. Do not leave the pen in a car on an exceptionally warm or cold day. Do not throw the pen with the needle attached.

Do not store away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Soliqua contains
- The active substances are insulin glargine and lixisenatide.
- Each pen contains 300 units insulin glargine and 150 micrograms lixisenatide in 3 ml of solution.

Each ml contains 100 units insulin glargine and 50 micrograms lixisenatide. Each dose step of Soliqua contains 1 unit of insulin glargine and 0.5 micrograms of lixisenatide.

The other ingredients are: glycerol 85%, methionine, metacresol, zinc chloride, concentrated hydrochloric acid and sodium hydroxide (for pH adjustment) and water for injections. See also section 2 "What you need to know before you use Soliqua" for information on sodium and metacresol.

What Soliqua looks like and contents of the pack
Soliqua is a clear and colourless solution for injection filled in a glass cartridge inserted in a SoloStar pre-filled pen. Each pen contains 3 ml of solution.

Packs of 3 and 5 pre-filled pens. Not all pack sizes may be marketed in your country.

Needles are not included in the pack.

Handwritten Arabic text: النشرة مطابقة للشهادة المرفقة بال CPP وقرار الشرح الخاص بالمشرفين بالـ C.19/15/19. Includes a stamp: ادارة تسجيل المستحضرات الصيدلانية لشهره مسنده التاريخ 15/19/19.

HYPERGLYCAEMIA AND HYPOLYCAEMIA

If you use insulin, you should always carry the following things with you:
- Foods containing sugar, such as dextrose tablets or a sugary drink (at least 20 grams).
- Information so that others know you have diabetes.

Hypoglycaemia (low blood sugar levels)
If your blood sugar level falls too much you may pass out (become unconscious). Serious hypoglycaemia may cause a heart attack or brain damage and may be life-threatening. You should learn to recognise the signs when your blood sugar is falling - so you can take action to stop it getting worse.

Reasons why hypoglycaemia may happen:
Examples include:
- You inject too much Soliqua.
- You miss meals or delay them.
- You do not eat enough, or eat food containing less carbohydrates than normal - artificial sweeteners are not carbohydrates.
- You drink alcohol - especially when you have not eaten much.
- You lose carbohydrates from being sick (vomiting) or diarrhoea.
- You are doing more exercise than usual or a different type of physical activity.
- You are recovering from an injury, operation or other stress.
- You are recovering from an illness or from fever.
- You are taking or have stopped taking certain other medicines (see section 2, "Other medicines and Soliqua").

Hypoglycaemia is also more likely to happen if:
- You have just started Soliqua treatment - if low blood sugar occurs, it may be more likely to happen in the morning.
- Your blood sugar levels are almost normal or are unstable.
- You change the area where you inject Soliqua. For example from the thigh to the upper arm.
- You have severe kidney or liver disease, or some other disease such as hypothyroidism.

Warning signs of hypoglycaemia
Thirst, increased need to urinate, tiredness, dry skin, reddening of the face, loss of appetite, low blood pressure, fast heartbeat, and urine test showing glucose and ketone bodies. Stomach pain, fast and deep breathing, feeling sleepy or passing out (becoming unconscious) may be signs of a serious condition (ketoacidosis) resulting from lack of insulin.

What to do if you experience hypoglycaemia
- Test your blood sugar level and, if it is high, as agreed with your doctor or nurse, test your urine for ketones as soon as you notice any of the above signs.
- Contact your doctor straight away if you have severe hypoglycaemia or ketoacidosis. This must always be treated by a doctor, normally in a hospital.

Reasons why hyperglycaemia may happen:
Examples include:
- You have not injected your Soliqua or not injected enough.
- Your medicine has become less effective - for example because it was not stored properly.
- You are doing less exercise than usual.
- You are under stress - such as emotional distress or excitement.
- You have an injury, infection or fever or have had an operation.
- You are taking or have taken certain other medicines (see section 2, "Other medicines and Soliqua").

Other side effects
Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

- Common: may affect up to 1 in 10 people
- Feeling dizzy
- Feeling sick (Nausea)
- Vomiting
- Diarrhoea

Uncommon: may affect up to 1 in 100 people
- Cold, runny nose, sore throat
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- Stomachache
- Tiredness
- Changes where the injection is given: If you inject Soliqua too often in the same place, you may develop dents at the site, caused by a loss of fat under the skin (lipatrophy) or you may develop lumps, caused by a build-up of fat under the skin (lipohypertrophy). The medicine may not work very well. Change the injection site with each injection to help prevent these changes.
- Skin and allergic reactions at the injection site: The signs may include reddening, unusually intense pain when injecting, itching, hives, swelling or inflammation. This can spread

When the signs of hypoglycaemia may be less clear:
The first warning signs of hypoglycaemia may change, be weaker or missing altogether if:
- You are elderly.
- You have had diabetes for a long time.
- You have a certain type of nerve damage (called "diabetic autonomic neuropathy").
- You have recently had too low blood sugar (for example the day before).
- Your low blood sugar comes on slowly.
- Your low blood sugar is always around "normal" or your diabetes control has greatly improved recently.
- You have recently changed from animal insulin to a manufactured insulin, like there is in Soliqua.
- You are taking or have taken certain other medicines (see section 2, "Other medicines and Soliqua").

In such cases, you may develop severe hypoglycaemia (and even pass out) before you know what is happening. Be familiar with your warning signs. If necessary, you might need to test your blood sugar more often. This can help to spot mild hypoglycaemic episodes. If you find it difficult to recognise your warning signs, you should avoid situations (such as driving a car) in which you or others would be put at risk by hypoglycaemia.

What to do if you experience hyperglycaemia
- Do not inject Soliqua. Take about 15 to 20 grams of sugar straight away - such as glucose, sugar cubes or a sugary drink. Drinks or foods that contain artificial sweeteners (such as diet drinks) do not help treat low blood sugar.
- You might then need to eat something (such as bread or pasta) that will raise your blood sugar over a longer time, especially if your next meal is not due. Ask your doctor or nurse if you are not sure which foods you should eat.
- With Soliqua, it may take longer to recover from low blood sugar because it contains a long-acting insulin (insulin glargine).

Table with 3 columns: Legend / Legend, Druckbare Farben / Printing colours, Technische Information / Technical information. Includes SAP-Nr., dimensions, and printing details.

Soliqua 100 units/ml + 50 micrograms/ml solution for injection in a pre filled pen (10-40). INSTRUCTIONS FOR USE

Read the Package Leaflet and these Instructions for Use first

Soliqua (10-40) pen contains insulin glargine and lisinsinamide. The combination of medicinal products in this pen is for the daily injection of 10 to 40 dose steps of Soliqua.

- Never re-use needles. If you do, you might not get your full dose (underdosing) or get too much (overdosing) as the needle could block.
- Never use a syringe to remove medicine from your pen. If you do, you may not get the correct amount of medicine.

Keep these Instructions For Use for future reference.

Important information

- Never share your pen – it is only for you
- Never use your pen if it is damaged or if you are not sure that it is working properly.
- Always perform a safety test (See STEP 3).
- Always carry a spare pen and spare needles in case they get lost or stop working.
- Always check the label of the pen before use to make sure you have the correct pen.

Learn to inject:

- Talk with your healthcare provider about how to inject, before using your pen.
- Ask for help if you have problems handling the pen, for example if you have problems with your sight.
- Read all of these instructions before using your pen. If you do not follow all of these instructions, you may get too much or too little medicine.

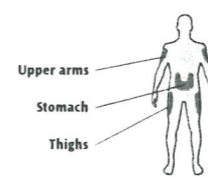
Need help?

If you have any questions about Soliqua, the pen or about diabetes, ask your doctor, pharmacist or nurse or call the local sanofi-aventis number.

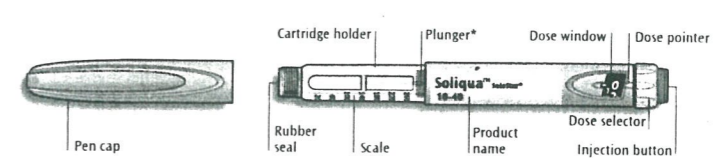
Extra items you will need:

- a new sterile needle (see STEP 2).
- a sharps container for used needles and pens. (see Throwing your pen away).

Places to inject



Get to know your pen



*You will not see the plunger until you have injected a few doses

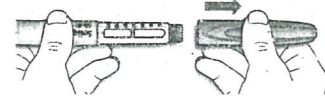
STEP 1: Check your pen

Take a new pen out of the refrigerator at least 1 hour before you inject. Injecting cold medication is more painful.

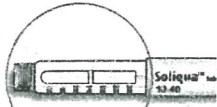
- A Check the name and expiry date on the label of your pen.**
- Make sure you have the correct medicine. This pen is peach coloured with an orange injection button.
 - Do not use this pen if you need a daily dose less than 10 dose steps or if you need more than 40 dose steps. Discuss with your doctor which pen is suitable for your needs.
 - Do not use your pen after the expiry date.



- B Pull off the pen cap.**



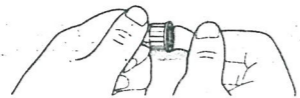
- C Check that the medicine is clear.**
- Do not use the pen if the medicine looks cloudy, coloured or contains particles.



STEP 2: Attach a new needle

- Do not reuse needles. Always use a new sterile needle for each injection. This helps stop blocked needles, contamination, and infection.
- Always use needles that are compatible for use with Soliqua pen.

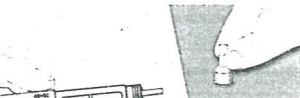
- A Take a new needle and peel off the protective seal.**



- B Keep the needle straight and screw it onto the pen until fixed. Do not over-tighten.**



- C Pull off the outer needle cap. Keep this for later.**



- D Pull off the inner needle cap and throw away.**



Handling needles

- Take care when handling needles to prevent needle injury and cross-infection.

STEP 3: Do a safety test

Always do a safety test before each injection to:

- Check your pen and the needle to make sure they are working properly
- Make sure that you get the correct dose.

- A Select 2 dose steps by turning the dose selector until the dose pointer is at the 2 mark.**



- B Press the injection button all the way in.**

- When medicine comes out of the needle tip, your pen is working correctly. The dose selector will be reset to "0".



If no liquid appears:

- You may need to repeat this step up to 3 times before seeing medicine.
- If no medicine comes out after the third time, the needle may be blocked. If this happens:
 - change the needle (see STEP 6 and STEP 2),
 - then repeat the safety test (STEP 3).
- Do not use your pen if there is still no medicine coming out of the needle tip. Use a new pen.
- Do not use a syringe to remove medicine from your pen.

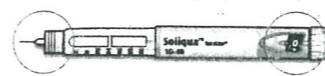
If you see air bubbles

- You may see air bubbles in the medicine. This is normal, they will not harm you.

STEP 4: Select the dose

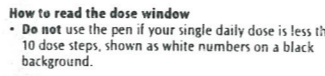
- Use this pen only to inject single daily doses from 10 to 40 dose steps.
- Do not select a dose or press the injection button without a needle attached. This may damage your pen.

- A Make sure a needle is attached and the dose is set to '0'.**



- B Turn the dose selector until the dose pointer lines up with your dose.**

- If you turn past your dose, you can turn back down.
- If there are not enough dose steps left in your pen for your dose, the dose selector will stop at the number of dose steps left.
- If you cannot select your full prescribed dose, use a new pen or inject the remaining dose steps and use a new pen to complete your dose. Only in this case, it is okay to inject a partial dose of less than 10 dose steps. Always use another Soliqua (10-40) pen to complete your dose and no other pen.



Units of medicine in your pen

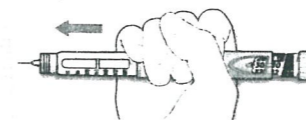
- Your pen contains a total of 300 dose steps. You can select your dose in steps of 1 dose step.
- Do not use this pen if you need a single daily dose that is less than 10 dose steps, or more than 40 dose steps.
- Each pen contains more than 1 dose.

STEP 5: Inject the dose

- If you find it hard to press the injection button in, do not force it as this may break your pen.
- Change the needle (see STEP 6 "Remove the needle" and STEP 2 "Attach a new needle") then do a safety test (see STEP 3).
- If you still find it hard to press in, get a new pen.
- Do not use a syringe to remove medicine from your pen.

- A Choose a place to inject as shown in the picture above.**

- B Push the needle into your skin as shown by your healthcare provider.**
- Do not touch the injection button yet.



- C Place your thumb on the injection button. Then press all the way in and hold.**
- Do not press at an angle. Your thumb could block the dose selector from turning.



- D Keep the injection button held in and when you see "0" in the dose window, slowly count to 10.**
- This will make sure you get your full dose.



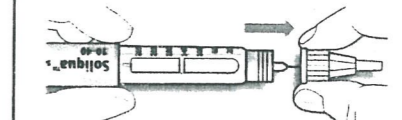
- E After holding and slowly counting to 10, release the injection button. Then remove the needle from your skin.**



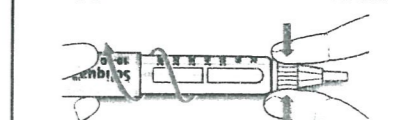
STEP 6: Remove the needle

- Take care when handling needles to prevent needle injury and cross-infection.
- Do not put the inner needle cap back on.

- A Grip the widest part of the outer needle cap. Keep the needle straight and guide it into the outer needle cap back. Then push firmly on.**
- The needle can puncture the cap if it is recapped at an angle.



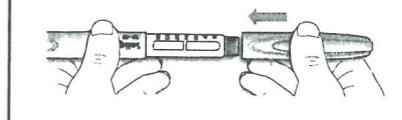
- B Grip and squeeze the widest part of the outer needle cap. Turn your pen several times with your other hand to remove the needle.**
- Try again if the needle does not come off the first time.



- C Throw away the used needle in a puncture resistant container (see "Throwing your pen away" at the end of these instructions for use).**



- D Put your pen cap back on.**
- Do not put the pen back in the refrigerator.



How to store your pen

- Before first use**
- Keep new pens in the refrigerator between 2°C to 8°C.
 - Do not freeze.

After first use

- Keep your pen at room temperature, below 30°C
- Do not put your pen back in the refrigerator.
- Do not store your pen with the needle attached.
- Store the pen with your pen cap on.
- Only use your pen for up to 14 days after its first use.

How to care for your pen

Handle your pen with care

- If you think that your pen may be damaged, do not try to fix it. Use a new one.

Protect your pen from dust and dirt

- You can clean the outside of your pen by wiping it with a damp cloth (water only).
- Do not soak, wash or lubricate the pen. This may damage it.

Throwing your pen away

- Remove the needle before throwing your pen away.
- Throw away your used pen as instructed by your pharmacist or local authority.

Legende / Legend

SAP-Nr. / Plant PM code: 536659A
Sprachvariante / Country code: 056
Version: 4
Datum / Date: 07.04.2017 UK

Abmessungen / Dimensions: 594 x 420 mm
Schriftgröße / Font size: 9 Pt
Zeilenabstand / Line spacing: 10 Pt
Seite / Page: 4/6

Druckbare Farben / Printing colours

Black ■
Yellow ■
Cyan ■
Magenta ■

Technische Information / Technical information

Kontur / Outline ■

سوليقا 100 وحدة / مل + 50 ميكروغرام / مل، محلول للحقن في قلم معبأ مسبقاً (10-40) دليل الاستعمال

اقرأ النشرة ودليل الاستعمال هذا قبل الاستعمال الأول

يحتوي قلم سوليقا (10-40) على الأنسولين الجلارجين والليكنوزيناليد. يهدف الجمع ما بين العنوين في هذا القلم إلى إعطاء حبة يومية من 10 إلى 40 خلوطة جرعة من سوليقا.

- لا تستعمل الإبر مجددة، إن هلت. لا تستعمل على جرعة كاملة (جرعة واحدة) أو في حياض جرعة مفرطة (جرعة زائدة) بسبب إمكانية انسداد الإبر.
- لا تصعب أبداً الدواء من القلم بواسطة محقنة. إن هلت، لا تستعمل على الجرعة الصحيحة من الدواء.
- استخدم دليل الاستعمال هذا للرجوع إليه لاحقاً.

معلومات مهمة

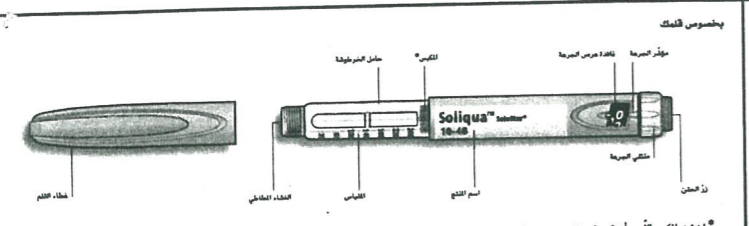
- لا تم أبداً بإعادة هيك - غير مختصن لك.
- لا تستعمل هيك أبداً إذا كان منسجراً، أو إذا لم تكن متأكدًا مما إذا كان يعمل كما يجب.
- قم دائماً بإجراء اختبار سلامة (راجع الخطوة 3).
- إسجل هيك دائماً هكاً احتياطياً وإجراء الاحتياطي في حال هلك القلم أو الإبر أو إذا لم تستعمل.

تلمذة الحقن

- اطلب من طبيبك أن يشرح لك كيفية الحقن قبل أن تستعمل هيك.
- اطلب المساعدة إذا كنت تعاني من مشاكل في استعمال القلم.
- مكثراً إذا كنت تعاني من مشاكل في الحقن.
- طبيبك أو الصيدلي الخاص بك أو الممرضين أو الفنيين الذين يدرسون الحقن يمكنهم مساعدتك على الحقن بشكل صحيح.
- إذا لم تستعمل هيك أبداً، فاستشر طبيبك.

هل تحتاج إلى مساعدة؟

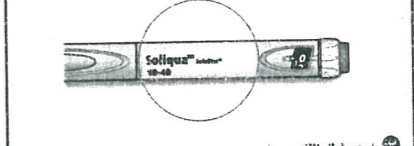
إذا كان لديك أسئلة حول سوليقا أو قلم الحقن أو إذا كنت بحاجة إلى مزيد من التعليمات، فراجع هكاً دليل الاستعمال.



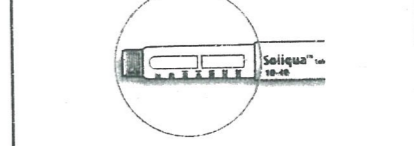
الخطوة 1: تحقق من هيك

أخرج هكاً جديداً من البراد قبل الحقن بساعة واحدة على الأقل. فحقن الدواء بارداً أكثر إبلاطاً.

- تحقق من الاسم وتاريخ انتهاء الصلاحية على صلافة هيك.
- تحقق من أن أدوية الدواء المتسحق. إن هذا القلم على أن الدواء الذي وزنته السنين برهاتين اثنين.
- لا تستعمل هذا القلم إذا كنت تحتاج إلى جرعة يومية أعلى من 10 خلوطات جرعة أو أكثر من 40 خلوطات جرعة. إسأل طبيبك عن القلم الذي يناسب حاجتك.
- لا تستعمل هيك بعد انتهاء تاريخ الصلاحية.



- إسحب هكاً من القلم.
- تحقق من أن الدواء صاف.
- لا تستعمل القلم إذا بدأ الدواء عكراً أو معلقاً أو يحتوي على شوائب.



الخطوة 2: ثبت إبرة جديدة

لا تستعمل مجددة الإبر. استعمل دائماً إبرة جديدة معقمة لكل عملية حقن. يهدف هذا الإجراء إلى منع كل خطر انسداد للإبرة والتلوث والتهيج.

- خذ إبرة جديدة واسحب الغريرة الوافية.
- أبق الإبرة موضع مستقيم وانحرفها على القلم إلى أن تصبح ثابتة. لا تقمها بشكل مفرط.
- إسحب هكاً من الإبرة الخارجي. احتفظ به لكي تستعمله لاحقاً.



- إسحب الهكاً الداخلي للإبرة وإزمه.
- التعامل مع الإبر: انتبه عندما تتعامل مع الإبر لتجنب خطر التعرض لحرق حرمسي ونقل العدوى.

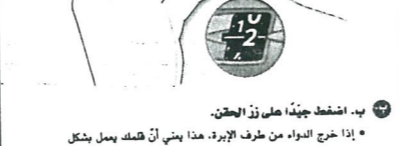


الخطوة 3: قم بإجراء اختبار سلامة

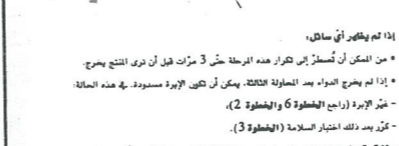
قم دائماً باختبار سلامة قبل كل عملية حقن بهدف:

- التأكد من أن هكاً والإبرة يعملان بشكل صحيح.
- التأكد من أنه تم حقن الجرعة الصحيحة.

- أقم باختبار جرعتين عبر أداة متلقي الجرعة إلى أن يصل مؤشر الجرعة عند مستوى الخط 2.
- بد. اضغط هكاً على زر الحقن.
- إذا خرج الدواء من طرف الإبرة، هذا يعني أن هكاً يعمل بشكل صحيح. سوف يعود متلقي الجرعة إلى 0.



- إذا لم يظهر أي هكاً، من الممكن أن تستجيب إلى تكرار هذه العملية حتى 3 مرات قبل أن ترى المنتج يخرج.
- إذا لم يخرج الدواء بعد المحاولة الثالثة، يمكن أن تكون الإبرة مسدودة. في هذه الحالة:
 - غير الإبرة (راجع الخطوة 6 والخطوة 2).
 - كرر بعد ذلك اختبار السلامة (الخطوة 3).
- لا تستعمل هكاً إذا لم يخرج الدواء من طرف الإبرة. استعمل هكاً جديداً.
- لا تصعب الدواء من هكاً بواسطة محقنة.



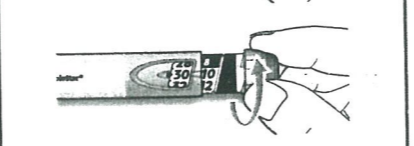
الخطوة 4: اختر الجرعة

استعمل هذا القلم فقط ليقن جرعات يومية تتراوح بين 10 و40 خلوطات جرعة.

- تأكد من أن الإبرة مثبتة بالقلم ومن أن الجرعة مضبوطة على 0.
- أدر متلقي الجرعة إلى أن يصبح مؤشر الجرعة بمحاذاة الجرعة المرغوب بها.

إذا تحسنت جرعتك عبر الإدارة بهيئاً جديداً، يمكنك العودة إلى الوراء. إذا لم يبق في القلم عدد كافٍ من الخلوطات لجرعتك، يتوقف متلقي الجرعات على هذه الخلوطات الجرعة الباقية في القلم. إذا لم يكن بإمكانك اختيار كامل جرعتك الموصوفة، استعمل هكاً جديداً أو احزن خلوطة الجرعة الباقية واستعمل القلم الجديد لإكمال جرعتك. في هذه الحالة فقط، يجب حقن جرعة جزئية أخرى من 10 خلوطة جرعة. استعمل دائماً هكاً سوليقا آخر (10-40) يكامل جرعتك، ولكن ليس هكاً آخر.

- كيف يجب قراءة نافذة الجرعة:
 - لا تستعمل القلم إذا كانت جرعتك اليومية أدنى من 10 خلوطة جرعة. هذه الأرقام مكتوبة بالأبيض على خلفية سوداء.



الخطوة 5: اخترن الجرعة

في حال واجهت صعوبات في دفع زر الحقن، لا تقمها بالقوة. هذا قد يتسبب بكسر هكاً. غير الإبرة (راجع الخطوة 6) "إسحب الإبرة" والخطوة 2 "ثبت إبرة جديدة" ثم قم بإجراء اختبار سلامة (راجع الخطوة 3).

- إذا كنت ما زالت تعاني من صعوبة في دفع زر الحقن، خذ هكاً جديداً.
- لا تستعمل محقنة لسحب الدواء من هكاً.
- اختر موقع حقن على النحو المشار إليه في الرسم أعلاه.
- أخذ الإبرة في جديك كما تحسنت طبيبتك.
- لا تقم به زر الحقن.

قم بتهيئة هكاً جديد على الجانب الأيمن من هكاً جديدة. هذا يعني أن هكاً جديد على الجانب الأيسر من هكاً جديدة. هذا يعني أن هكاً جديد على الجانب الأيسر من هكاً جديدة.

- أبق زر الحقن مطروقا وعندما ترى 0، في 2000 عرض الجرعة. حد يبعده حتى 10.
- بعد أن تكون جاهزاً لزر الحقن مطروقا وعددت يبعده حتى 10، اقلب زر الحقن. إسحب بعد ذلك الإبرة من جديك.



الخطوة 6: إسحب الإبرة

إنتهه عندما تتعامل مع الإبر لتفادي كل خطر جرح حرمسي وانتقال العدوى. لا تد وضع هكاً الإبرة الداخلي.

- أمسك بالقسم الأكبر من الهكاً الخارجي للإبرة. أمسك الإبرة بشكل مستقيم وأعد وضع هكاً الإبرة الخارجي على الإبرة. ثم اضغط بثبات. يمكن أن تنقب الإبرة المنطأ إذا أعيد وضع هذا الأخير بشكل منحرف.
- أمسك بالقسم الأكبر من هكاً الإبرة الخارجي. وباليد الأخرى، أدر هكاً مرات عدة لفك الإبرة.
- كرر المحاولة إذا لم تستطع فك الإبرة منذ المرة الأولى.



- إزم الإبرة المتصلة في حاوية مقاومة للتلوث (راجع قدر التخصن من القلم في نهاية دليل الاستعمال هذا).
- أعد وضع هكاً من القلم.
- لا تد وضع القلم في البراد.



بإدارة المؤسسة الصيدلانية
إدارة التسجيل المستحضرات الحيوية
نشره معتمده
تاريخه 19/11/19

حفظ القلم

قبل الاستعمال الأول:

- استخدم القلم في حرارة الغرفة التي لا تتخطى 30 درجة مئوية.
- لا تد وضع هكاً في البراد.
- لا تحفظ هكاً الإبرة مثبتة عليه.
- استخدم هكاً مع هكاً الموصوع عليه.
- استعمل هكاً فقط في خلال 14 يوماً بعد أن تم استخدامه لأول مرة.

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- استعمل هكاً فقط في خلال 14 يوماً بعد أن تم استخدامه لأول مرة.

تفاعل مع هكاً معوية:

- إذا كنت تتخذ أن هكاً منسجراً، لا تحاول تسليطه. لا تستعمل هكاً جديداً.

احم هكاً من الجفاف والفتارة:

- بمكثراً تحفظ هكاً من الجفاف بواسطة غطاء هكاً رطبة (مع الماء فقط). لا تلمس هكاً بالماء ولا تسلمه ولا تزيته. لهذا قد يتسبب له الحرق.

أسباب الإبرة قبل أن ترمي هكاً:

- إزم هكاً المتصل على التحو الذي أرساه به الصيدلي أو مستطاف الهكاً.

وزارة الصحة والسكان
 الادارة المركزية لشؤون الصيدلة
 ادارة تسجيل المستحضرات الصيدلانية
 ملاحظات مرقمة تاريخ 14/05/2018
 د/ماكي ابراهيم

<MAT>S41641



GTIN 03582910081005

SN
 Lot/batch :
 Fab/Mfg :
 EXP :

Pour un usage individuel uniquement.
 Toujours utiliser une aiguille neuve.

Chaque stylo prérempli contient 300 unités d'insuline glargine et 150 microgrammes de lixisénatide dans une solution de 3 ml.
 Chaque ml contient 100 unités d'insuline glargine et 50 microgrammes de lixisénatide.
 Chaque étape de dosage contient 1 unité d'insuline glargine et 0,5 mcg de lixisénatide.

Excipients : glycérol 85%, méthionine, métacresol, chlorure de zinc, acide chlorhydrique, hydroxyde de sodium (pour ajustement de pH), eau pour préparations injectables.

Lire la notice avant utilisation.
 TENIR HORS DE LA VUE ET DE LA PORTEE DES ENFANTS.
 N'utiliser que des solutions claires et incolores.

Avant première utilisation
 A conserver au réfrigérateur (entre 2°C et 8°C). Ne pas congeler ou placer près du compartiment congélateur ou d'une poche de congélation.
 Conserver le stylo prérempli dans l'emballage extérieur à l'abri de la lumière.

Après première utilisation
 A conserver à une température ne dépassant pas 30°C. Ne pas mettre au réfrigérateur. Ne pas congeler.
 Ne pas conserver le stylo avec l'aiguille fixée dessus.
 Conserver le stylo à l'abri de la chaleur directe ou de la lumière directe. Remettez le capuchon sur le stylo après chaque injection afin de le protéger de la lumière.

For single patient use only.
 Always use a new needle.

Each pen contains 300 units of insulin glargine and 150 micrograms of lixisenatide in 3 ml solution.
 Each ml contains 100 units of insulin glargine and 50 micrograms of lixisenatide.
 Each dose step contains 1 unit of insulin glargine and 0,5 mcg of lixisenatide.

Excipients: glycerol 85%, methionine, metacresol, zinc chloride, hydrochloric acid, sodium hydroxide (for pH adjustment), water for injections.

Read the package leaflet before use.
 KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
 Use only clear, colourless solution.

Not in-use pens
 Store in a refrigerator (2°C - 8°C). Do not freeze or place next to the freezer compartment or a freezer pack.
 Keep the pen in the outer carton in order to protect from light.

In-use pens
 Stored below 30°C. Do not refrigerate. Do not freeze.
 Store the pen away from direct heat or direct light. The pen cap must be put back on the pen after each injection in order to protect from light.



3 582910 081005

لا استعمال في مرض واحد فقط.
 استعمال ابرة جديدة دائما.

يحتوي كل قلم على 300 وحدة من الأنسولين غلارجين وعلى 150 ميكروغرام من الليكسيناتيد. لا يحل محل 3 مل.
 يحتوي كل ميليلتر على 100 وحدة من الأنسولين غلارجين وعلى 50 ميكروغرام من الليكسيناتيد.
 تحتوي كل خطوة معايرة جرعة على وحدة واحدة من الأنسولين غلارجين وعلى 0,5 ميكروغرام من الليكسيناتيد.

المواد الحافظة: غليسرول 85%، ميثيونين، ميتاكريسول، كلوريد الزنك، حمض الهيدروكلوريك، هيدروكسيد الصوديوم (لضبط الرقم الهيدروجيني)، ماء مقطر.

اقرأ النشرة قبل الاستخدام.
 إبعاد الدواء بعيداً عن متناول الأطفال ومشتاويهم.
 استعمال قلم الحاقن الجديد والتدعيم اللين.

الأقلام غير المستخدمة
 إحتفظ بالأقلام في البرد (بين درجتين مئويتين ودرجات مئوية). لا تجمدها ولا تشعها قرب النيران أو حرارة الشمس.
 إحتفظ بالقلم في العبوة الخارجية لحماية من الضوء.

الأقلام قبل الاستخدام
 إحتفظها في حرارة ما دون 30 درجة مئوية.
 لا تشعها في البرد. لا تجمدها.
 إحتفظ بالقلم بعيداً عن الحرارة المباشرة أو الضوء المباشر.
 يجب إعادة وضع الغطاء على القلم بعد كل حقنة حتى تحميه من الضوء.

RESPECTER LES DOSES PRESCRITES.
 USE THE DOSE AS PRESCRIBED.
 Uniquement sur ordonnance.
 Prescription only medicine.
 دواء بوصف طبية فقط.

Source the product
 If you combine with other
 medicines, ask your doctor
 or pharmacist.
 Be very careful!
 Do not use without advice
 from your doctor.
 إن كنت تتناول دواء آخر مع
 هذا الدواء، فاستشر طبيبك
 أو الصيدلي.

Sanofi-aventis groupe
 54, rue La Boétie
 75008 Paris
 France
 Sanofi-aventis Deutschland GmbH
 Industriepark Höchst
 65926 Frankfurt am Main
 Germany
 After first use:
 Use within 14 days.
 After première utilisation:
 à utiliser dans les 14 jours.

SOLIQUA™ SoloStar®

100 unités/ml + 50 microgrammes/ml
 100 units/ml + 50 micrograms/ml
 سوليكا™ "سولوستار" 100 وحدة/مل + 50 ميكروغرام/مل

Solution injectable en stylo prérempli
 Solution for injection in a pre-filled pen
 محلول للحقن في قلم ممتلئ مسبقاً

insuline glargine + lixisénatide
 insulin glargine + lixisenatide
 أنسولين غلارجين + ليكسيناتيد

10-40 étapes de dosage
 dose steps
 10-40 خطوة معايرة الجرعة

(خطوة واحدة معايرة الجرعة، dose step, 1 étape de dosage)
 = 1 unité d'insuline glargine + 0,5 microgrammes de lixisénatide
 = 1 unit of insulin glargine + 0,5 micrograms of lixisenatide
 = وحدة واحدة من الأنسولين غلارجين + 0,5 ميكروغرام من الليكسيناتيد

A injecter exclusivement à l'aide de ce stylo.
 Use only in this pen.
 للاستعمال حصراً في هذا القلم

Voie sous-cutanée
 Subcutaneous use
 للحقن تحت الجلد

3 x 3 ml stylos / pens / أقلام



Ouvrir ici / Open here / إفتح هنا

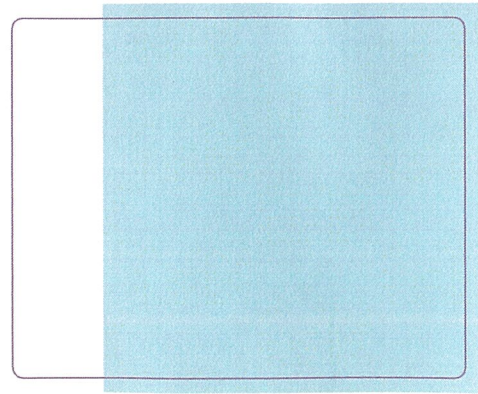
- يتم الالتزام بطباعة ماني:
- رقم التسجيل وتاريخ الإنتاج وتاريخ انتهاء الصلاحية (يوم - شهر - سنة).
- سعر البيع للجمهور كما ورد في إخطار التسجيل.
- اسم المستورد في مصر وعنوانه.

| Legende / Legend | Druckbare Farben / Printing colours | Technische Information / Technical information |
|---|-------------------------------------|--|
| SAP-Nr. / Plant PM code: 541641 | Pantone Black C | Lackfrei / Unvarnished area |
| Sprachvariante / Country code: 056 | Pantone 1225 C | Stanze / Die |
| Version: 1 | Pantone 186 C | |
| Datum / Date: 04.07.2018 PE | Pantone 151 C | |
| Abmessungen / Dimensions: 172 x 85 x 25 mm | | |
| Kleinste verwendete Schriftgröße / Minimum point size of text: 6,5 pt | | |
| Seite / Page: 1/1 | | |

وزارة الصحة والسكان
 الادارة المركزية لتقنين الصيدلة
 ادارة تسجيل المستحضرات الصيدلانية
 رقم ترخيص: 14 / 6 / 14
 تاريخ: 14 / 6 / 14

د. مكيه ابراهيم

الإلتزام بطباعة رقم التشعيلة وتاريخ الإنتاج وتاريخ إنتهاء الصلاحية (يوم - شهر - سنة).



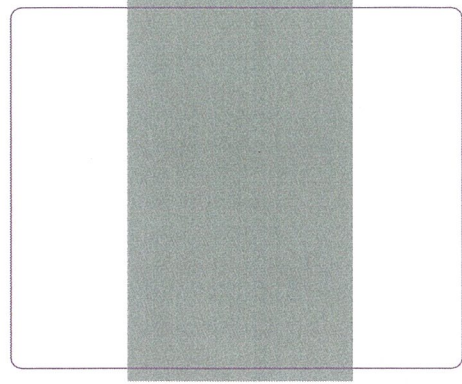
540933 <MAT> Lot/Batch: Fab/Mfg: EXP:

SOLIQUA™ SoloStar® 3 ml

100 unités/ml + 50 mcg/ml
 100 units/ml + 50 mcg/ml

سولين الجارجين - ليكسيناتيد / Insulin glargine + lixisenatide /
 Solution injectable / injection / حقن / حقن

• **Toujours utiliser une aiguille neuve.**
 • **Always use a new needle. Subcutaneous use**
 • **10-40 étapes de dosage / dose steps /**
 Sanofi-Aventis Deutschland GmbH



| | | |
|--|--|--|
| <p>Legende / Legend</p> <p>SAP-Nr. / Plant PM code: 540933 Sprachvariante / Country code: 056 Version: 1 Datum / Date: 26.02.2018 AR Abmessungen / Dimensions: 62,1 × 49,5 mm Kleinste verwendete Schriftgröße / Minimum point size of text: 6 pt Seite / Page: 1/1</p> | <p>Druckbare Farben / Printing colours</p> <p>Pantone Black C Pantone 1225 C Pantone 186 C Weiss / white</p> | <p>Technische Information / Technical information</p> <p>Kontur / Contour Lumilack / Lumiphore coating</p> |
|--|--|--|