Prescribing Information: REPEVAX® Suspension for injection in pre-filled syringe, Diphtheria, Tetanus, Pertussis (acellular, component) and Poliomyelitis (inactivated) Vaccine (adsorbed, reduced antigen(s) content)

Please refer to the Summary of Product Characteristics (SPC) before prescribing.

Presentation: 0.5 mL single dose of vaccine supplied in prefilled syringe. Each dose of vaccine contains ≥2 IU Diphtheria Toxoid, ≥20 IU Tetanus Toxoid, 2.5 µg Pertussis Toxoid,
5 µg Filamentous Haemagglutinin, 5 µg Fimbriae Types 2 and 3, 3 µg Pertactin, 29 D antigen units of inactivated type 1 (Mahoney) poliovirus, 7 D antigen units of inactivated type 2 (MEF1) poliovirus, 26 D antigen units of inactivated type 3 (Saukett) poliovirus and 1.5 milligrams of aluminium phosphate as adjuvant

Indication: Active immunisation against diphtheria, tetanus, pertussis and poliomyelitis in persons from the age of three years as a booster following primary immunisation. Passive protection against pertussis in early infancy following maternal immunisation during pregnancy.

Dosage and Administration: All indicated age groups should receive one 0.5 mL dose, according to official recommendations. The vaccine should be administered by the intramuscular route, the preferred site is into the deltoid muscle. REPEVAX should not be administered into the gluteal area; intradermal or subcutaneous routes should not be used (in exceptional cases the subcutaneous route may be considered). Do not administer by intravascular or intradermal injection. REPEVAX can be used for repeat vaccination to boost immunity to diphtheria, tetanus and pertussis at 5 to 10 year intervals. REPEVAX can be used in the management of tetanus prone injuries with or without concomitant administration of Tetanus Immunoglobulin according to official recommendations.
REPEVAX may be administered to pregnant women during the second or third trimester to provide passive protection of infants against pertussis.

Contraindications: REPEVAX should not be administered to individuals who have previously had a hypersensitivity reaction to any vaccine containing diphtheria or tetanus toxoids, poliomyelitis viruses or pertussis (acellular or whole cell), to any residual substances carried over from manufacture (formaldehyde, glutaraldehyde, streptomycin, neomycin, polymyxin B and bovine serum albumin) or to any other component of the vaccine (Phenoxyethanol, Polysorbate 80, Ethanol and adjuvant). REPEVAX should not be administered to persons who experienced an encephalopathy of unknown origin within 7 days of previous immunisation with a pertussis-containing vaccine. As with other vaccines, administration of REPEVAX should be postponed in persons suffering from an acute severe febrile illness. The presence of a minor infection (e.g. mild upper respiratory infection) is not a contraindication.

Precautions and Warnings: REPEVAX should not be used for primary immunisation. Appropriate facilities and medication should be available in the event of anaphylaxis. If Guillain-Barré syndrome has occurred within 6 weeks of receipt of prior vaccine containing tetanus toxoid, the decision to give any vaccine containing tetanus toxoid, including REPEVAX, should be based on careful consideration of the potential benefits and possible risks. Immunogenicity of the vaccine may be reduced by immunosuppressive treatment or immunodeficiency. REPEVAX should not be administered to persons with a progressive or unstable neurological disorder, uncontrolled epilepsy or progressive encephalopathy until a treatment regimen has been established and the condition has been stabilized. Intramuscular injections should be given with care in patients on anticoagulant therapy or suffering from coagulation disorders because of the risk of haemorrhage. In these situations and following official recommendations the administration of REPEVAX by deep subcutaneous injection may be considered, although there is a risk of increased local reactions. A persistent nodule at the site of injection may occur with all adsorbed vaccines, particularly if administered into the superficial layers of the subcutaneous tissue. REPEVAX contains 1.01 milligram of alcohol (ethanol) in each 0.5 mL dose. The small amount of alcohol in this medicine will not have any noticeable effects. In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Pregnancy*:* REPEVAX can be used during the second or third trimester of pregnancy in accordance with official recommendations. As with other inactivated vaccines, it is not expected that vaccination with REPEVAX during any trimester would harm the fetus. *Immunogenicity in pregnant women*: Pertussis antibody responses in pregnant women are generally similar to those in non pregnant women. Vaccination during the second or third trimester of pregnancy is optimal for antibody transfer to the developing fetus. *Effectiveness against pertussis in infants born to women vaccinated during pregnancy*: The vaccine effectiveness in the first 2-3 months of life for infants born to women vaccinated against pertussis during the third trimester of pregnancy has been evaluated in 3 observational studies. The overall effectiveness is > 90%.

Breastfeeding: The effect of administration of REPEVAX during lactation has not been assessed. Nevertheless, as REPEVAX contains toxoids or inactivated antigens, no risk to the breastfed infant should be expected. The benefits versus the risk of administering REPEVAX to breastfeeding women should be evaluated by the health-care providers.

Fertility: REPEVAX has not been evaluated in fertility studies.

Adverse Reactions: Side effects in children aged 3-6 years include: Very common *(≥1/10)*: diarrhoea, fatigue/asthenia and fever, injection site reactions (pain, swelling and erythema). Common *(≥1/100 to <1/10)*: headache, vomiting, nausea, rash, arthralgia/joint swelling, irritability, injection site reactions (dermatitis, bruising and pruritus). Side effects in adolescents and adults include: Very common *(≥1/10)*: headache, nausea, arthralgia/joint swelling, myalgia, fatigue/asthenia and

chills, injection site reactions (pain, swelling and erythema). Common *(≥1/100 to <1/10)*: diarrhoea, vomiting and fever. The following have also been reported in all age groups (i.e. children 3-6, adolescents and adults) (*frequency not known*): pain in vaccinated limb, dizziness, abdominal pain, malaise, pallor and injection site induration. Serious side effects have been reported (*frequency not known*) including lymphadenopathy, anaphylactic reactions such as urticaria, face oedema and dyspnea, extensive limb swelling, transient paresthesia/hypoesthesia of vaccinated limb, convulsions, vasovagal syncope, facial palsy, myelitis, brachial neuritis and Guillain-Barré syndrome. For a complete list of undesirable effects please refer to the Summary of Product Characteristics.

List price: Single pack containing one prefilled syringe. NHS cost £20.00.

Legal Category: POM

Marketing Authorisation Number: PL46602/0005

Marketing Authorisation Holder: Sanofi Pasteur Europe, 14 Espace Henry Vallée, 69007 Lyon, France.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Sanofi Tel: 0800 0902314.
Alternatively, send via E-mail to UK-drugsafety@sanofi.com