Abbreviated Aprovasc SmPC

APROVASC®

GENERIC NAME: Irbesartan/Amlodipine Besilate

DOSAGE FORM AND FORMULATION: TABLET FORMULA: Each tablet contains:

Irbesartan	150 mg	300 mg	300 mg
Amlodipine besilate equivalent to Amlodipine	5 mg	5 mg	10 mg
Excipient qs	1 tablet	1 tablet	1 tablet

THERAPEUTIC INDICATION:

Treatment of essential arterial hypertension. APROVASC® is indicated in hypertensive adult patients whose blood pressure could not be adequately controlled with Irbesartan or Amlodipine monotherapy.

CONTRAINDICATIONS: Due to the presence of both, Irbesartan and amlodipine, APROVASC® is contraindicated in:

Hypersensitivity to irbesartan, amlodipine, dihydropyridines or to any formulation component

Shock (including cardiogenic shock).

Obstruction of the left ventricular outflow tract (e.g. clinically significant aortic stenosis).

Unstable angina (excluding Prinzmetal's angina).

Haemodynamically unstable heart failure following an acute myocardial infarction.

Severe hypotension.

Pregnancy and lactation *(see General precautions (Warnings) and Restrictions during pregnancy and lactation)*.

Do not co-administer APROVASC® with medications containing aliskiren in patients with diabetes or with moderate to severe renal impairment (Glomerular Filtration Rate (GFR) <60 mL/min/1.73 m^2).

Do not co-administer APROVASC® with angiotensin-converting enzyme inhibitors (ACEIs) in patients with diabetic nephropathy.

GENERAL PRECAUTIONS and WARNINGS

Hypotension (Patients with volume depletion)-Hypoglycaemia-Foetal/neonatal morbidity and mortality-Patients with heart failure

Hepatic impairment.

Pregnancy: There are no adequate and well-controlled studies in pregnant women. APROVASC® is contraindicated during pregnancy. APROVASC® should not be used in women with a potential risk of pregnancy unless effective contraceptive measures are being used

Lactation: APROVASC® is contraindicated in lactation (*see Contraindications*).

SECONDARY AND ADVERSE REACTIONS:

For irbesartan: Common: Dizziness, headache, Nausea/vomiting, Fatigue, edema**.** (**For more information read the full SmPC)**

For amlodipine: Common Dizziness, headache, drowsiness, Visual disturbances (including diplopia), Palpitations, Flushing, Dyspnea, Nausea Abdominal pain Indigestion, Change in bowel habits (including diarrhea and constipation)**.** (**For more information read the full SmPC)**

DRUG-DRUG AND OTHER INTERACTIONS:

For Irbesartan and amlodipine combination: Based on a pharmacokinetic study where Irbesartan and amlodipine were administered alone or in combination, there is no pharmacokinetic interaction between Irbesartan and amlodipine.

No drug interaction studies have been conducted with APROVASC® and other medicinal products.

For Irbesartan

Angiotensin-converting enzyme inhibitors (ACE inhibitors). Repaglinide. Lithium. (For more information read the full SmPC)

For Amlodipine:

Cimetidine. Grapefruit juice. Sildenafil. Atorvastatin. Digoxin. Warfarin. (For more information read the full SmPC)

DOSAGE AND ADMINISTRATION ROUTE:

The usual, initial, and maintenance dose of APROVASC® is one tablet once a day. It can be administered with or without food.

APROVASC® should be administered in patients whose blood pressure is not adequately controlled during monotherapy with Irbesartan or amlodipine or for continued treatment for patients receiving Irbesartan and amlodipine as separate tablets. Dose should be individualized based on the response to therapy with individual components and the required antihypertensive response. The maximum recommended dose of APROVASC® is 300 mg/10 mg daily.

SPECIAL POPULATIONS

Pediatric patients: Safety and efficacy of APROVASC® has not been established., ***Elderly patients and patients with renal failure:*** It is usually not necessary to reduce the dosage in elderly patients or in patients with impaired renal function (regardless of grade).,**Patients with impaired hepatic function:** Due to the presence of amlodipine, APROVASC ® should be administered with caution (*see General precautions*).

MARKETING AUTHORISATION HOLDER: Sanofi Aventis de México, S.A. de C.V.
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To report an adverse event or if you have any medical enquiry, please call +964 751 740 2599 or email us at:
Levant.Pharmacovigilance@sanofi.com for adverse events
Levant.medinfo@sanofi.com for medical enquiries
Quality.Levant@sanofi.com for product technical complaints

Always refer to the full Summary of Product Characteristics (SmPC) before prescribing.

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