APROVEL® Abridged Prescribing Information

NAME AND PRESENTATION: Aprovel 150 mg and Aprovel 300 mg tablets, contain 150 mg and 300 mg of irbesartan respectively. **THERAPEUTIC INDICATIONS:** Aprovel is indicated in adults for the treatment of essential hypertension. It is also indicated for the treatment of renal disease in adult patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen. **POSOLOGY AND METHOD OF ADMINISTRATION:** The usual recommended initial and maintenance dose is 150 mg once daily, with or without food. In patients insufficiently controlled with 150 mg once daily, the dose of Aprovel can be increased to 300 mg, or other anti-hypertensive agents can be added. In hypertensive type 2 diabetic patients, therapy should be initiated at 150 mg once daily and titrated up to 300 mg once daily as the preferred maintenance dose for treatment of renal disease. *Intravascular volume depletion*: should be corrected prior to administration of Aprovel. *Elderly*: dosage adjustment is not usually necessary although consideration should be given to initiating therapy at 75mg when over 75 year old. *Renal or Hepatic impairment*: no dosage adjustment with mild to moderate hepatic impairment. There is no clinical experience in patients with severe hepatic impairment. No dosage adjustment is necessary in patients with impaired renal function but a lower starting dose (75 mg) should be considered when haemodialysis. *Paediatric population*: safety and efficacy in patients from 0 to 18 years old has not beenestablished**. CONTRA-INDICATIONS:** Hypersensitivity to the active substance or to any of the excipients**.** 2nd and 3rd trimester of pregnancy. Hypersensitivity to any component of the product. Concomitant use of Aprovel with aliskiren-containing products in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m2).**SPECIAL WARNINGS AND PRECAUTIONS FOR USE:** Intravascular volume depletion ,renovascular hypertension, renal impairment and kidney transplantation, hypertensive patients with type 2 diabetes and renal disease, dual blockade of the renin-angiotensin-aldosterone system (RAAS), hyperkalemia, hypoglycemia, Lithium, aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy, primary aldosteronism (see full SmPC). **PREGNANCY:** The use of AIIRAs is not recommended during the first trimester of pregnancy. The use of AIIRAs is contraindicated during the second and third trimesters of pregnancy**. BREAST-FEEDING:** No information is available regarding the use of Aprovel during breast-feeding. Aprovel is not recommended and alternative treatments with better established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant. It is unknown whether irbesartan or its metabolites are excreted in human milk. **DRUG INTERACTIONS:** diuretics and other antihypertensive agents, aliskiren containing products or ACE-I, potassium supplement and potassium – sparing diuretics, lithium, NSAIDs, repaglinide (see full SmPc). **EFFECTS ON ABILITY TO DRIVE:** When driving vehicles or operating machines, it should be taken into account that dizziness or weariness may occur during treatment. **UNDESIRABLE EFFECTS:** The incidence of adverse events was not related to dose, gender, age, race or duration of treatment. Commonly reported adverse reactions were dizziness, orthostatic dizziness, orthostatic hypotension, nausea/vomiting, musculoskeletal pain, and fatigue(see full SmPc) . **OVERDOSAGE:** Experience in adults exposed to doses of up to 900 mg/day for 8 weeks revealed no toxicity. No specific antidote. The patient should be closely monitored, and the treatment should be symptomatic and supportive. Irbesartan is not removed by haemodialysis. **SHELF LIFE :** 3 years. **SPECIAL PRECAUTIONS FOR STORAGE :** Do not store above 30°C.**MARKETING AUTHORISATION HOLDER:** Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly, France. **DATE OF REVISION OF THE TEXT:** January 2023.

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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