

Package leaflet: Information for the user

SANOFI 

APROVEL® 75 mg

film-coated tablets

irbesartan

Read all of this leaflet carefully before you start taking 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.
- 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 Aprovel is and what it is used for
2. What you need to know before you take Aprovel
3. How to take Aprovel
4. Possible side effects
5. How to store Aprovel
6. Contents of the pack and other information

1. WHAT APROVEL IS AND WHAT IT IS USED FOR

Aprovel belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels causing them to tighten. This results in an increase in blood pressure. Aprovel prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower. Aprovel slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Aprovel is used in adult patients

- to treat high blood pressure (*essential hypertension*)
- to protect the kidney in patients with high blood pressure, type 2 diabetes and laboratory evidence of impaired kidney function.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE APROVEL

Do not take Aprovel

- if you are **allergic** to irbesartan or any other ingredients of this medicine (listed in section 6)
- if you are **more than 3 months pregnant**. (It is also better to avoid Aprovel in early pregnancy – see pregnancy section)
- **if you have diabetes or impaired kidney function** and you are treated with a blood pressure lowering medicine containing aliskiren

Warnings and precautions

Talk to your doctor before taking Aprovel and **if any of the following apply to you:**

- if you get **excessive vomiting or diarrhoea**
- if you suffer from **kidney problems**
- if you suffer from **heart problems**
- if you receive Aprovel for **diabetic kidney disease**. In this case your doctor may perform regular blood tests, especially for measuring blood potassium levels in case of poor kidney function
- if you are **going to have an operation** (surgery) or **be given anaesthetics**
- if you are taking any of the following medicines used to treat high blood pressure:
 - an ACE-inhibitor (for example enalapril, lisinopril, ramipril) in particular if you have diabetes-related kidney problems.
 - aliskiren

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading “Do not take Aprovel”.

You must tell your doctor if you think you are (or might become) pregnant. Aprovel is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Children and adolescents

This medicinal product should not be used in children and adolescents because the safety and efficacy have not yet been fully established.

Other medicines and Aprovel

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may need to change your dose and/or to take other precautions:

If you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Aprovel” and “Warnings and precautions”).

You may need to have blood checks if you take:

- potassium supplements
- salt substitutes containing potassium
- potassium-sparing medicines (such as certain diuretics)
- medicines containing lithium

If you take certain painkillers, called non-steroidal anti-inflammatory drugs, the effect of irbesartan may be reduced.

Aprovel with food and drink

Aprovel can be taken with or without food.

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Aprovel before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Aprovel. Aprovel is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Aprovel is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Aprovel is unlikely to affect your ability to drive or use machines. However, occasionally dizziness or weariness may occur during treatment of high blood pressure. If you experience these, talk to your doctor before attempting to drive or use machines.

Aprovel contains lactose. If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicinal product.

3. HOW TO TAKE APROVEL

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Method of administration

Aprovel is for **oral use**. Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water). You can take Aprovel with or without food. Try to take your daily dose at about the same time each day. It is important that you continue to take Aprovel until your doctor tells you otherwise.

• Patients with high blood pressure

The usual dose is 150 mg once a day (two tablets a day). The dose may later be increased to 300 mg (four tablets a day) once daily depending on blood pressure response.

• Patients with high blood pressure and type 2 diabetes with kidney disease

In patients with high blood pressure and type 2 diabetes, 300 mg (four tablets a day) once daily is the preferred maintenance dose for the treatment of associated kidney disease.

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those on **haemodialysis**, or those **over the age of 75 years**.

The maximal blood pressure lowering effect should be reached 4-6 weeks after beginning treatment.

Use in children and adolescents

Aprovel should not be given to children under 18 years of age. If a child swallows some tablets, contact your doctor immediately.

If you take more Aprovel than you should:

If you accidentally take too many tablets, contact your doctor immediately.

If you forget to take Aprovel:

If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

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

Some of these effects may be serious and may require medical attention.

As with similar medicines, rare cases of allergic skin reactions (rash, urticaria), as well as localised swelling of the face, lips and/or tongue have been reported in patients taking irbesartan. If you get any of these symptoms or get short of breath, **stop taking Aprovel and contact your doctor immediately**.

The frequency of the side effects listed below is defined using the following convention:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Side effects reported in clinical studies for patients treated with Aprovel were:

- Very common (may affect more than 1 in 10 people): if you suffer from high blood pressure and type 2 diabetes with kidney disease, blood tests may show an increased level of potassium.
- Common (may affect up to 1 in 10 people): dizziness, feeling sick/vomiting, fatigue and blood tests may show raised levels of an enzyme that measures the muscle and heart function (creatinine kinase enzyme). In patients with high blood pressure and type 2 diabetes with kidney disease, dizziness when getting up from a lying or sitting position, low blood pressure when getting up from a lying or sitting position, pain in joints or muscles and decreased levels of a protein in the red blood cells (haemoglobin) were also reported.
- Uncommon (may affect up to 1 in 100 people): heart rate increased, flushing, cough, diarrhoea, indigestion/heartburn, sexual dysfunction (problems with sexual performance), chest pain.

Some undesirable effects have been reported since marketing of Aprovel. Undesirable effects where the frequency is not known are: feeling of spinning, headache, taste disturbance, ringing in the ears, muscle cramps, pain in joints and muscles, reduced number of platelets, abnormal liver function, increased blood potassium levels, impaired kidney function, inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis) and severe allergic reactions (anaphylactic shock). Uncommon cases of jaundice (yellowing of the skin and/or whites of the eyes) have also been reported.

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.

United Kingdom

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.



Ireland

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE APROVEL

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 blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw 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 Aprovel contains

- The active substance is irbesartan. Each tablet of Aprovel 75 mg contains 75 mg irbesartan.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hypromellose, silicon dioxide, magnesium stearate, titanium dioxide, macrogol 3000, carnauba wax. Please see section 2 "Aprovel contains lactose".

What Aprovel looks like and contents of the pack

Aprovel 75 mg film-coated tablets are white to off-white, biconvex, and oval-shaped with a heart debossed on one side and the number 2871 engraved on the other side.

Aprovel 75 mg film-coated tablets are supplied in blister packs of 14, 28, 30, 56, 84, 90 or 98 film-coated tablets. Unidose blister packs

of 56 x 1 film-coated tablet for delivery in hospitals are also available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

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

Manufacturer:

SANOFI WINTHROP INDUSTRIE
1, rue de la Vierge
Ambarès & Lagrave
F-33565 Carbon Blanc Cedex - France

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Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu/>

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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