

Package leaflet: Information for the user
Aprovel® 75mg 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.

The name of your medicine is Aprovel 75mg film coated tablets but will be referred to as Aprovel throughout this leaflet

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
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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

Warning 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 develop **low blood sugar levels** (symptoms may include sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heartbeat), particularly if you are being treated for diabetes.
- 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.

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Aprovel. Your doctor will decide on further treatment. Do not stop taking Aprovel on your own.

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
- repaglinide (medication used for lowering blood sugar levels)

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.

Aprovel contains sodium. This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

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 150mg once a day (two tablets a day). The dose may later be increased to 300mg (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, 300mg (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.
- Rare (may affect up to 1 in 1,000 people): intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea.

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, decreased number of red blood cells (anaemia – symptoms may include tiredness, headaches, being short of breath when exercising, dizziness and looking pale), 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), severe allergic reactions (anaphylactic shock) and low blood sugar levels. 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. 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**.

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

5. How to store Aprovel

Keep out of the sight and reach of children.

Do not store above 30°C.

Do not take the tablets after the expiry date which is stated on the carton and blister labels after 'Exp'. The expiry date refers to the last day of that month.

Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Aprovel contains

The active ingredient in the aprovel is irbesartan.

Each tablet contains 75mg irbesartan.

The other ingredients are lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hypromellose, silicon dioxide, magnesium stearate, titanium dioxide, macrogol 3000 and carnauba wax. Please see section 2 'Aprovel contains lactose'.

What Aprovel looks like and contents of the pack

Aprovel is 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 is available in pack size of 28 tablets.

Manufactured by:

Sanofi Winthrop Industrie, 1, rue de la Vierge, Ambares & Lagrave, F-33565 Carbon Blanc Cedex - France.

OR

Sanofi Winthrop Industrie, 30-36 Avenue Gustave Eiffel, BP 7166, F-37071 Tours Cedex 2 – France.

Procured from within the EU and repackaged by the Product

Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Aprovel® 75mg film coated tablets; PL 18799/3238

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