

APROVEL[®] FILM-COATED TABLET

Irbesartan (150 mg & 300 mg)

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What Aprovel is used for

Aprovel is used

- 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.

How Aprovel works

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.

Before you use Aprovel

- When you must not use it

- if you are **allergic** (hypersensitive) to irbesartan or any other ingredients of Aprovel
- 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

Aprovel should not be given to children and adolescents (under 18 years).

- Before you start to use it

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 medicine.

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

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Aprovel does not usually interact with 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 "When you must not use it" and "Things to be careful of").

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.

Taking Aprovel with food and drink

Aprovel can be taken with or without food.

How to use Aprovel

Always take Aprovel exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- How much to use

Aprovel is for **oral use**. Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water).

- **Patients with high blood pressure**

The usual dose is 150 mg once a day. The dose may later be increased to 300 mg 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 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**. If a lower starting dose is considered necessary, the 150 mg tablet not being breakable, alternative therapy should be considered.

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

- When to use it

You can take Aprovel with or without food. Try to take your daily dose at about the same time each day.

- How long to use it

It is important that you continue to take Aprovel until your doctor tells you otherwise.

- If you forget to use it

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 product, ask your doctor or pharmacist.

- If you use too much (overdose)

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

Children should not take Aprovel

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

While you are using it

- Things you must do

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.

- Things you must not do

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).

- Things to be careful of

Tell your doctor 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 heart beat), 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

- 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.

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.

Side effects

Like all medicines, Aprovel 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 localized 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: if you suffer from high blood pressure and type 2 diabetes with kidney disease, blood tests may show an increased level of potassium.
- Common: dizziness, feeling sick/vomiting, fatigue and blood tests may show raised levels of an enzyme that measures the muscle and heart function (creatin 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: 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), and 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 been reported.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Aprovel

- Storage

Keep out of the reach and sight of children.

Do not use Aprovel 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.

- Disposal

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.

Product Description

- What it looks like?

Aprovel 150 mg film-coated tablets White to off-white, biconvex, and oval-shaped with a heart debossed on one side and the number '2872' engraved on the other side.

Aprovel 300 mg film-coated tablets White to off-white, biconvex, and oval-shaped with a heart debossed on one side and the number '2873' engraved on the other side.

- Ingredients

-Active ingredients:

Aprovel 150 mg film-coated tablets Each film-coated tablet contains 150 mg of irbesartan.

Aprovel 300 mg film-coated tablets Each film-coated tablet contains 300 mg of irbesartan.

-Inactive ingredients:

Lactose monohydrate,
microcrystalline cellulose,
croscarmellose sodium,
hypromellose, silicon dioxide,
magnesium stearate, titanium
dioxide, macrogol 3000, carnauba
wax.

- MAL Numbers:

Aprovel 150 mg film-coated
tablets: MAL19990971AZ

Aprovel 300 mg film-coated
tablets: MAL19990972AZ

Manufacturer

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

Product Registration Holder

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