



Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. What Aprovel is and what it is used for
2. Before you take Aprovel
3. How to take Aprovel
4. Possible side effects
5. How to store Aprovel
6. Further information

1. WHAT APROVEL IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group

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.

Therapeutic indications

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. BEFORE YOU TAKE APROVEL

Contraindications

Do not take Aprovel

- 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).

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

Appropriate precautions for use; special warnings

Take special care with Aprovel

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 are **going to have an operation** (surgery) or **be given anaesthetics**.

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).

Use in Children

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

Using 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.

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.

Taking 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

No studies on the effects on the ability to drive and use machines have been performed. 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.

Important information about some of the ingredients of Aprovel

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.

3. HOW TO TAKE APROVEL

Always take Aprovel exactly as your doctor has told you. You should 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. 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**.

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

If you take more Aprovel than you should:

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.

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 product, ask your doctor or pharmacist.

4. POSSIBLE 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 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: at least 1 in 10 patients or more.

Common: at least 1 in 100 and less than 1 in 10 patients.

Uncommon: at least 1 in 1000 and less than 1 in 100 patients.

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 (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: 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, abnormal liver function, increased blood potassium levels, impaired kidney function, and inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis). Uncommon cases of jaundice (yellowing of the skin and/or whites of the eyes) have also 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.

5. HOW TO STORE APROVEL

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.

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. FURTHER INFORMATION

What Aprovel contains

- The active substance is irbesartan. Each tablet of Aprovel 300 mg contains 300 mg irbesartan.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hypromellose, silicon dioxide, magnesium stearate, titanium dioxide, macrogol 3000, carnauba wax.

What Aprovel looks like and contents of the pack

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

Aprovel 300 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 PHARMA BRISTOL MYERS SQUIBB SNC
174 avenue de France - F-75013 Paris - France

Manufacturer:

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

This leaflet was last approved in May 2011