PLEASE READ ALL OF THE LEAFLET CAREFULLY BEFORE TAKING THIS MEDICINE.
- Keep this leaflet you may need to read it again.
- If you have any other questions or doubts, ask your doctor or pharmacist for further information.
- This medicine has been prescribed personally for you. Do not give it to anybody else, even if he/she has identical symptoms since it might cause harm to him/her.

COMPOSITION
The active substance in Aprovel tablets is irbesartan. Each tablet contains 150 mg irbesartan. The tablets contain the following excipients: microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, hypromellose, silicon dioxide, magnesium stearate, titanium dioxide (E 171), macrogol, carnauba wax. Aprovel 150 mg film-coated tablets are supplied in blister packs of 14, 28, 56 or 98. Unidose blister packs of 56 tablets for delivery in hospitals are also available. Not all pack sizes may be marketed.

TYPE OF MEDICINE
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.

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 et Lagrave
33565 Carbon Blanc cedex - France

WHEN SHOULD Aprovel BE USED?
Aprovel is used in the treatment of high blood pressure (hypertension) and for the protection of the kidney in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function.
Your doctor measured your blood pressure and found it to be above the normal range for your age. High blood pressure, if not treated, can damage blood vessels in several organs such as the heart, the kidneys, the brain and the eyes. In some instances this may lead to heart attacks, heart or kidney failure, strokes, or blindness. There are usually no symptoms of high blood pressure before damages occur. Thus measurement of the blood pressure is necessary to verify if it is in the normal range or not. High blood pressure can be treated and controlled with medicines such as Aprovel. Your doctor may also have recommended that you adjust your lifestyle to help to lower your high blood pressure (losing weight, avoiding smoking, reducing alcohol consumption and restricting the amount of salt in the diet). He may also have encouraged the practice of regular, mild (not strenuous) exercise such as walking and swimming.
In addition to blood sugar control and blood pressure control that may need other concomitant medicines, Aprovel is used for the treatment of kidney disease in patients with high blood pressure and type 2 diabetes.

WHEN SHOULD Aprovel NOT BE USED?
Do not take Aprovel if:
- you are in the second or third trimester of pregnancy,
- you are breast-feeding or
- if you are allergic to any of the ingredients (see "Composition").

OTHER IMPORTANT INFORMATION BEFORE TAKING Aprovel
There are certain conditions which you may have, or have had, which require special care before or while taking Aprovel. Therefore, before taking this medicine, you should have told your doctor if you suffer from:
- excessive vomiting or diarrhea,
- kidney problems,
- heart problems.

If you are to undergo any surgery or receive anaesthetics, you should make sure the doctor knows that you are taking Aprovel tablets.
CAN YOU TAKE Aprovel WITH OTHER MEDICINES?
You should have informed your doctor of any medicines you are taking. These include medicines obtained without prescription. Aprovel does not usually interact with other medicines. Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium-containing salt substitutes, potassium-sparing medicines (such as certain diuretics) or lithium-containing medicines.

As with other blood pressure lowering drugs, the effect of irbesartan may be reduced when you take non-steroidal anti-inflammatory drugs.

CAN Aprovel BE USED DURING PREGNANCY OR BREAST-FEEDING?
Tell your doctor before taking Aprovel if you are pregnant, think you may be pregnant, are planning to be pregnant or if you are breast-feeding. It is preferable not to use Aprovel in the first trimester of pregnancy. If you become pregnant while on Aprovel treatment, refer to your doctor without delay. Aprovel should not be taken during the second or third trimester of pregnancy, or while breast-feeding (see “when should Aprovel not be used?”). A switch to a suitable alternative treatment should be carried out in advance of a planned pregnancy.

CAN I DRIVE OR OPERATE MACHINERY WHILE TAKING Aprovel?
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, consult your doctor before attempting such activities.

HOW SHOULD YOU TAKE Aprovel?
The tablets should be taken regularly as directed by your doctor. Treatment usually starts with 150 mg once a day. The dose may later be increased to 300 mg once daily depending on blood pressure response. The maximal blood pressure lowering effect should be reached 4-6 weeks after beginning treatment. If you have the impression that the effect of Aprovel is too strong or too weak, talk to your doctor or pharmacist.

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. Aprovel can be taken with or without food. The tablets should be swallowed with a drink of water. You should 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. Aprovel should not be given to children (<18 years).

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

OVERDOSE
If you accidentally take too many tablets, or a child swallows some, contact your doctor immediately.

ARE THERE UNDESIRABLE EFFECTS WHEN TAKING Aprovel?
All medicines may cause some undesirable effects. If any undesirable effects occur, they are likely to be mild and temporary. However, some effects may be serious and require medical attention.

The following side effects have been commonly reported in patients with high blood pressure in clinical studies: dizziness, feeling sick/vomiting, fatigue and increased plasma creatine kinase level. The following less common side effects have also been reported: fast heart beat, flushing, cough, diarrhea, indigestion, problems with sexual performance and chest pain. In patients with high blood pressure and type 2 diabetes with renal disease, the following additional common side effects have been reported in clinical studies: low blood pressure and dizziness (especially when getting up from a lying or sitting position), pain in bones and muscles as well as decrease in haemoglobin (pigment in red blood cells). Increased blood potassium level has been very commonly reported. Occasional undesirable effects reported since marketing of Aprovel are: headache, taste disturbance, ringing in the ears, pain in joints and muscles, liver function disorders, increased blood potassium levels and impaired renal function. As with similar medicines, rare cases of allergic skin reactions (rash, urticaaria), as well as localised swelling of the face, lips and/or tongue have been reported in patients taking irbesartan. If you think you are developing such a reaction or get short of breath stop taking Aprovel and seek immediate medical attention.

If you notice any other undesirable effects, you should inform your doctor or pharmacist and ask for their advice.

HOW SHOULD YOU STORE YOUR Aprovel TABLETS?
Keep all medicines out of the reach and sight of children. Aprovel tablets should be stored below 30°C. Store in the original package. You will see an “Expiry date” on the carton and on the blister. Do not use the tablets after this date. Do not remove the tablets from the blister pack until you are ready to take the medicine.

DATE OF LAST REVISION OF THIS LEAFLET
August 2005
Leaflet Aprovel RM 150 mg
28 tablets
Pakistan

Pantone Reflex Blue CVC 100 % + 65 %
+ dégradé de 55% à 22%