

INFORMATION FOR THE PATIENT

AVAPRO®

(irbesartan)

Tablets, 75, 150 and 300 mg

Serious Warning and Precautions

AVAPRO (irbesartan) should not be used during pregnancy. If you discover that you are pregnant while taking AVAPRO, stop the medication and please contact your physician.

What is AVAPRO?

AVAPRO belongs to a class of drugs known as angiotensin II AT₁ receptor blockers which have been proven to be effective in lowering blood pressure.

AVAPRO comes in the form of an oval shaped white tablet which contains irbesartan as the active ingredient. In addition, AVAPRO tablets contain the following non-medicinal ingredients: lactose, microcrystalline cellulose, pregelatinized starch, croscarmellose sodium, silicon dioxide, poloxamer 188 and magnesium stearate.

Why has my physician prescribed AVAPRO?

Your physician has prescribed AVAPRO because you have a condition known as hypertension or high blood pressure. Your physician may have also prescribed AVAPRO if you have high blood pressure and type 2 diabetes mellitus to protect your kidney function.

What is blood pressure?

Blood pressure is the force of blood against the walls of your arteries (blood vessels that carry blood away from the heart). You need some blood pressure for the blood to circulate through your body. If the blood pressure gets too high, it is called high blood pressure or hypertension.

Your blood pressure changes during the day depending on activity, stress and excitement.

How is blood pressure measured?

Blood pressure is measured in millimeters of mercury (mm Hg) and is recorded as two numbers, for instance 120/80 (read as one hundred and twenty over eighty). The upper number is the *systolic* pressure and the lower number is the *diastolic* pressure.

The systolic pressure is the pressure in the arteries when the heart beats. The diastolic pressure is the pressure in the arteries when the heart relaxes between beats.

What is high blood pressure or hypertension?

You have high blood pressure or hypertension if your blood pressure is persistently higher than the normal limits, even when calm or relaxed.

How do I know if I have high blood pressure?

There are usually no symptoms of high blood pressure. The only way of knowing that you have hypertension is to know your blood pressure. For that reason, you should have your blood pressure checked on a regular basis.

Why should high blood pressure be treated?

Left untreated, high blood pressure can damage vital organs like the heart and kidneys. You may feel fine and have no symptoms, but eventually hypertension can lead to strokes, heart attacks, heart failure, kidney failure or blindness.

What is kidney disease in patients with hypertension and type 2 diabetes mellitus?

When the kidneys deteriorate, they allow protein to pass in the urine. Early kidney disease is measured by detection of protein in the urine [microalbuminuria (MAU)] while more advanced stages are measured by increased levels of protein in urine (proteinuria). The presence of an abnormal protein level in the urine is a major risk factor for the progression of kidney disease (e.g. initiation of dialysis, kidney transplant) and heart disease.

How does AVAPRO treat high blood pressure?

AVAPRO lowers blood pressure by specifically blocking a natural substance called angiotensin II, which normally narrows your blood vessels. Treatment with AVAPRO allows the blood vessels to relax. Although your physician will be able to tell you that the medicine is working by measuring your blood pressure, you will probably feel no different while you are taking AVAPRO.

If your blood pressure remains too high after an adequate trial period, your physician may decide to increase the dose of AVAPRO. AVAPRO reduces blood pressure further when the dose is increased. This may avoid the need for an additional medication to control your blood pressure.

If I have hypertension and Type 2 diabetes, how can AVAPRO treat my condition?

In addition to controlling and lowering your blood pressure, recent studies have shown that AVAPRO protects your kidneys by reducing protein in the urine. This in turn slows the progression of your kidney disease.

Who should not take AVAPRO?

Do not take Avapro if:

- **You are pregnant, breast-feeding or thinking of becoming pregnant**

Taking AVAPRO during pregnancy can cause injury and even death to your baby. This medicine should not be used during pregnancy. If you are planning to become pregnant while taking AVAPRO, contact immediately your doctor.

It is possible that AVAPRO passes into breast milk. You should discuss with your doctor about taking AVAPRO while breast-feeding.

- If you are allergic to any of the ingredients.

AVAPRO should not be given to children.

If any of the above apply to you, inform your doctor or pharmacist first and ask for their advice.

Other Important Information Before Taking AVAPRO

There are certain conditions which you may have, or have had, which require special care before or while taking AVAPRO. Therefore, before taking this medicine, you should tell your doctor if you think any of the following applies to you:

- a) You suffer from low blood pressure;
- b) You are taking a “water pill”;
- c) You are vomiting or have severe diarrhea;
- d) You are on a particular diet - low on salt;
- e) You are on dialysis;
- f) You have kidney problems.

If you are to undergo any surgery or receive anaesthetics, you should make sure your doctor knows that you are taking AVAPRO.

Can I take AVAPRO with other medications?

Tell your doctor if you are taking other medications.

Do not take any other medications, including over-the-counter products, unless you have discussed the matter with your doctor. Certain medications tend to increase your blood pressure, for example, preparations for appetite control, asthma, colds, coughs, hay fever and sinus problems. Certain medications, known as NSAIDs (Non-steroidal anti-inflammatory drugs, including COX 2 inhibitors), could reduce the effect of antihypertensive medications such as AVAPRO. These medicines, used to reduce pain and swelling, include ibuprofen, naproxen and celecoxib.

Can I drive or operate machinery while using AVAPRO?

Almost all patients can, but you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you respond to your medicine.

How should I take AVAPRO?

Take AVAPRO every day exactly as your physician has instructed. It is important to continue taking AVAPRO for as long as your physician prescribes it in order to maintain control of your blood pressure.

AVAPRO may be taken with or without food.

What should I do if I miss a dose?

Try to take AVAPRO daily as prescribed. If you miss a dose, do not take an extra dose. Just resume your normal schedule.

What should I do in case of an overdose?

Contact your physician immediately so that medical attention can be given promptly.

What undesirable effects may AVAPRO have?

Along with its intended action, any medication, including AVAPRO, may cause side effects. Most patients do not have side effects from taking AVAPRO, but if you notice any of the following or any other unusual symptoms tell your pharmacist or your doctor right away:

- Dizziness
- Lightheadedness
- Rash
- Being tired
- Diarrhea
- Muscle pain.

Side effects such as myalgia (muscle pain), myasthenia (muscle weakness), myositis (muscle inflammation) and rhabdomyolysis (a muscle-wasting disease), in rare cases leading to kidney failure, have been reported with the use of angiotensin II receptor blockers, the class of drugs to which AVAPRO belongs. You should contact your physician promptly if you experience muscle pain that you cannot explain, muscle tenderness or weakness, generalised weakness, or when you notice dark/brown urine.

Keep in mind that...

AVAPRO has been prescribed to you for your current medical problem only. Do not give it to other people.

AVAPRO should be stored at room temperature (15° to 30 °C).

Keep this medication out of the reach of children.

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