

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrAVAPRO®

Irbesartan tablets

Read this carefully before you start taking **AVAPRO** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **AVAPRO**.

Serious Warnings and Precautions

AVAPRO should not be used during pregnancy. Taking AVAPRO during pregnancy can cause injury or even death to your baby. If you discover that you are pregnant while taking AVAPRO, stop the medication and contact your healthcare professional as soon as possible.

What is AVAPRO used for?

- AVAPRO is used in adults to lower high blood pressure. It can be used alone or together with a thiazide diuretic (a “water pill”).
- If you have high blood pressure, type 2 diabetes and kidney disease, AVAPRO may help to protect kidney function.

How does AVAPRO work?

AVAPRO is an angiotensin receptor blocker (ARB). It lowers blood pressure. This medicine does not cure your disease. It helps to control it. Therefore, it is important to continue taking AVAPRO regularly even if you feel fine.

What are the ingredients in AVAPRO?

Medicinal ingredients: Irbesartan.

Non-medicinal ingredients: Carnauba wax, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol 3000, silicon dioxide and titanium dioxide.

AVAPRO comes in the following dosage forms:

Tablets 75 mg, 150 mg and 300 mg.

Do not use AVAPRO if you:

- are allergic to irbesartan or to any non-medicinal ingredient in the formulation.
- have experienced an allergic reaction (angioedema) with swelling of the hands, feet, or ankles, face, lips, tongue, throat, or sudden difficulty breathing or swallowing, to any ARB. Be sure to tell your healthcare professional that this has happened to you.
- have diabetes or kidney disease and are already taking:
 - a blood pressure-lowering medicine that contains aliskiren (such as RASILEZ®)

- an angiotensin converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because their medicinal ingredient ends in ‘-PRIL’.
- are pregnant or intend to become pregnant. Taking AVAPRO during pregnancy can cause injury and even death to your baby.
- are breastfeeding. It is possible that AVAPRO passes into breast milk.
- have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption
 because lactose is a non-medicinal ingredient in AVAPRO.

AVAPRO is not for use in children and adolescents (under the age of 18 years).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take AVAPRO. Talk about any health conditions or problems you may have, including if you:

- have experienced an allergic reaction to any drug used to lower blood pressure, including angiotensin converting enzyme (ACE) inhibitors.
- have narrowing of an artery or a heart valve.
- have had a heart attack or stroke.
- have heart failure.
- have liver or kidney disease.
- have diabetes. AVAPRO may cause low blood sugar levels.
- have psoriasis or a history of psoriasis
- are on dialysis.
- are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- are taking a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill” that makes your body keep potassium).
- are on a low-salt diet.
- are taking a medicine that contains aliskiren, such as RASILEZ[®], used to lower high blood pressure. The combination with AVAPRO is not recommended.
- are taking an angiotensin converting enzyme (ACE) inhibitor. The combination with AVAPRO is not recommended.
- are taking a medicine that contains lithium. The combination with AVAPRO is not recommended.

Other warnings you should know about:

Before surgery and general anesthesia (even at the dentist’s office), tell the doctor or dentist that you are taking AVAPRO, as there may be a sudden fall in blood pressure associated with general anesthesia.

Allergic Reactions: Allergic reactions (swelling of areas of tissue under the skin, sometimes affecting the face and throat, hives and severe allergic reactions) have been reported. Stop taking AVAPRO and get immediate medical help if you experience any symptoms of an allergic reaction.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to AVAPRO. Dizziness, lightheadedness, or fainting can occur, especially after the first dose and when the dose is increased.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with AVAPRO:

- Agents increasing serum potassium, such as a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”).
- Lithium used to treat bipolar disease.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Blood pressure-lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. RASILEZ®), or angiotensin converting enzyme (ACE) inhibitors.
- Certain medications tend to increase your blood pressure, for example, preparations for appetite control, asthma, colds, coughs, hay fever and sinus problems.
- Medicines used to lower blood sugar levels, including insulin and oral medicines, such as repaglinide.

How to take AVAPRO:

- Take AVAPRO every day exactly as prescribed.
- It is recommended to take your dose at about the same time every day.
- AVAPRO may be taken with or without food.

Usual adult dose:

Recommended Initial Dose: 150 mg once a day.

Your healthcare professional can increase the dosage to 300 mg once daily if required.

Overdose:

If you think you, or a person you are caring for, have taken too much AVAPRO, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you have forgotten to take your dose during the day, carry on with the next dose at the usual time. Do not double the dose.

What are possible side effects from using AVAPRO?

These are not all the possible side effects you may have when taking AVAPRO. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- dizziness
- drowsiness, insomnia, being tired
- rash
- diarrhea, vomiting
- headache
- back or leg pain, muscle cramps
- lightheadedness
- ringing in the ears

AVAPRO can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Increased levels of potassium in the blood: irregular heartbeats, muscle weakness, generally feeling unwell		X	
Increased levels of creatine phosphokinase: blood tests may show raised levels of an enzyme that measures breakdown of muscle (creatine phosphokinase)			X
UNCOMMON			
Low blood pressure: dizziness, fainting, light-headedness. May occur when you go from lying or sitting to standing up.	X		
Edema: swelling of hands, ankles, or feet		X	
Tachycardia: fast heart beat		X	
Liver problems: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		X	
Kidney problems: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		X	
RARE			
Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine		X	
Allergic reaction and angioedema: rash, hives, swelling of the face, lips, tongue or throat, difficulty			X

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
swallowing or breathing			
VERY RARE			
Decreased platelets: bruising, bleeding, fatigue and weakness, small purple or red dots under the skin		X	
UNKNOWN			
Skin problems: psoriasis, increased skin sensitivity to sunlight		X	
Low blood sugar: sweating, weakness, hunger, dizziness, trembling, headache			X
Anemia (decreased number of red blood cells): fatigue, loss of energy, looking pale, weakness, shortness of breath		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store AVAPRO tablets at room temperature (15 to 30°C).

Keep out of reach and sight of children.

If you want more information about AVAPRO:

- Talk to your healthcare professional

- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.sanofi.ca, or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

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