

PART III: CONSUMER INFORMATION

IRBESARTAN

(Irbesartan Tablets)
Manufacturer's Standard

Read this carefully before you start taking IRBESARTAN and each time you get a refill. This leaflet is a summary and will not tell you everything about IRBESARTAN. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about IRBESARTAN.

ABOUT THIS MEDICATION

What the medication is used for:

- IRBESARTAN lowers high blood pressure
- If you have high blood pressure, type 2 diabetes and kidney disease, IRBESARTAN may help to protect kidney function

What it does:

IRBESARTAN is an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”.

This medicine does not cure your disease. It helps to control it. Therefore, it is important to continue taking IRBESARTAN regularly even if you feel fine.

When it should not be used:

Do not take IRBESARTAN 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 doctor, nurse, or pharmacist 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 IRBESARTAN during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. It is possible that IRBESARTAN passes into breast milk.

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

What the medicinal ingredient is:

Irbesartan.

What the nonmedicinal ingredients are:

Colloidal silicon dioxide, copovidone, croscarmellose sodium, hydroxy propylcellulose, polysorbate, polyvinyl alcohol, macrogol, sodium stearyl fumarate, talc and titanium dioxide.

What dosage forms it comes in:

Tablets, 75mg, 150 mg, and 300 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions-Pregnancy
IRBESARTAN should not be used during pregnancy. If you discover that you are pregnant while taking IRBESARTAN, stop the medication and contact your physician as soon as possible.

BEFORE you use IRBESARTAN talk to your doctor or pharmacist 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 diabetes, liver or kidney disease.
- Have psoriasis or a history of psoriasis
- Are on dialysis.
- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.

IMPORTANT: PLEASE READ

- 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 IRBESARTAN is not recommended.
 - Are taking an angiotensin converting enzyme (ACE) inhibitor. The combination with IRBESARTAN is not recommended.
 - Are taking a medicine that contains lithium. The combination with IRBESARTAN is not recommended.
 - Are less than 18 years old.
- 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.

PROPER USE OF THIS MEDICATION

Take IRBESARTAN exactly as prescribed. It is recommended to take your dose at the same time every day.

Do not stop taking your medication without having first informed your doctor.

Usual Adult dose:

High Blood Pressure (hypertension) including in patients with Type 2 Diabetes Mellitus:

Recommended Initial Dose: 150 mg once a day

Your doctor can increase the dosage to 300 mg once daily when required.

IRBESARTAN may be taken with or without food.

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

Overdose:

If you think you have taken too much IRBESARTAN contact your doctor, nurse, pharmacist, 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 one at the usual time. Do not double dose.

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

Please remember:

- If you are to undergo any surgery or receive anaesthetics, you should make sure your doctor knows that you are taking IRBESARTAN.
- Hypersensitivity reactions (swelling of areas of tissue under the skin, sometimes affecting the face and throat, hives and severe allergic reactions have been reported).

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with IRBESARTAN:

- 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

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

If any of these affects you severely, tell your doctor, nurse or pharmacist.

IRBESARTAN can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell		✓	
	Low blood pressure: Dizziness/ Fainting/ Light-headedness	✓		
Uncommon	Jaundice (Liver disorder): yellowing of the		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite			
Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		✓	
Rare	Rhabdomyolysis is: muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine		✓
	Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Very Rare	Decreased Platelets: bruising, bleeding, fatigue and weakness		✓	
	Skin reaction: psoriasis, increased skin sensitivity to sunlight		✓	
Unknown	Decreased platelet count, sometimes associated with purple spots or bruises on the skin		✓	

This is not a complete list of side effects. If you have any unexpected effects while taking IRBESARTAN, contact your doctor or pharmacist.

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/adverse-reaction-reporting.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.

HOW TO STORE IT

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

Keep out of the reach and sight of children.

MORE INFORMATION

This document plus the full Product Monograph prepared for health professionals can be found by contacting Sanis Health Inc. at:

1-866-236-4076
or quality@sanis.com

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