

PART III: CONSUMER INFORMATION

Pr **IRBESARTAN/HCTZ**
irbesartan and hydrochlorothiazide
Manufacturer's Standard

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

ABOUT THIS MEDICATION

What the medication is used for:

IRBESARTAN/HCTZ lowers high blood pressure.

What it does:

IRBESARTAN/HCTZ is a combination of 2 drugs, irbesartan and hydrochlorothiazide:

- Irbesartan is an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “**SARTAN**”. It lowers blood pressure.
- Hydrochlorothiazide is a diuretic or “water pill” that increases urination. This lowers blood pressure.

This medicine does not cure high blood pressure. It helps to control it. Therefore, it is important to continue taking IRBESARTAN/HCTZ regularly even if you feel fine.

When it should not be used:

Do not take IRBESARTAN/HCTZ if you:

- Are allergic to irbesartan or hydrochlorothiazide or to any non-medicinal ingredient in the formulation.
- Are allergic to any sulfonamide-derived drugs (sulfa drugs); most of them have a medicinal ingredient that ends in “**MIDE**”.
- 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 (any drug in the same class as irbesartan). Be sure to tell your doctor, nurse or pharmacist that this has happened to you.
- Have difficulty urinating or produce no urine.
- 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/HCTZ during pregnancy can cause injury and even death to your baby
- Are breast-feeding. IRBESARTAN/HCTZ passes into breast milk.
- Have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorptionbecause lactose is a non-medicinal ingredient in IRBESARTAN/HCTZ.

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

What the medicinal ingredients are:

Irbesartan and hydrochlorothiazide

What the important nonmedicinal ingredients are:

IRBESARTAN/HCTZ 150/12.5 and 300/12.5 mg tablets contain the following nonmedicinal ingredients: black iron oxide, croscarmellose sodium, hydroxyl propyl methyl cellulose, iron oxide red, lactose monohydrate, lecithin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, sodium stearyl fumarate, talc, titanium dioxide and yellow iron oxide

IRBESARTAN/HCTZ 300/25 mg tablets also contain black iron oxides, and pregelatinized starch.

What dosage forms it comes in:

Tablets in three strengths:

IRBESARTAN/HCTZ 150/12.5 mg tablets are peach coloured, oval shaped, biconvex, film-coated, tablets embossed with “rph” on one side and “I33” on the other side.

IRBESARTAN/HCTZ 300/12.5 mg tablets are peach coloured, oval shaped, biconvex, film-coated, tablets embossed with “rph” on one side and “I32” on the other side.

IRBESARTAN/HCTZ 300/25 mg tablets are brown coloured, oval, biconvex, film-coated, tablets embossed with “rph” embossed on one side and “I31” on the other side.

WARNINGS AND PRECAUTIONS

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

BEFORE you use IRBESARTAN/HCTZ tell your doctor, nurse, or pharmacist if you:

- Are allergic to any drug used to lower blood pressure, including angiotensin converting enzyme (ACE) inhibitors,

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or penicillin.

- 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 gout, or lupus erythematosus.
- 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 IRBESARTAN/HCTZ is not recommended
- Are taking an angiotensin converting enzyme (ACE) inhibitors. The combination with IRBESARTAN/HCTZ is not recommended.
- Are less than 18 years old
- Have had skin cancer or have a family history of skin cancer.
- Have a greater chance of developing skin cancer because you have light-coloured skin, get sunburned easily, or are taking drugs to suppress your immune system.

Risk of skin cancer:

- IRBESARTAN/HCTZ contains hydrochlorothiazide. Treatment with hydrochlorothiazide may increase the risk of developing non-melanoma skin cancer. The risk is higher if you have been taking IRBESARTAN/HCTZ for many years (more than 3) or at a high dose.
- While taking IRBESARTAN/HCTZ:
 - Make sure to regularly check your skin for any new lesions. Check areas that are most exposed to the sun, such as the face, ears, hands, shoulders, upper chest and back.
 - Limit your exposure to the sun and to indoor tanning. Always use sunscreen (SPF-30 or higher) and wear protective clothing when going outside.
 - Talk to your doctor immediately if you get more sensitive to the sun or UV light or if you develop an unexpected skin lesion (such as a lump, bump, sore, or patch) during the treatment.

Hydrochlorothiazide in IRBESARTAN/HCTZ can cause Sudden Eye Disorders:

- **Myopia:** sudden nearsightedness or blurred vision
- **Glaucoma:** an increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss.

These eye disorders are related and can develop within hours to weeks of starting IRBESARTAN/HCTZ.

You may become sensitive to the sun while taking IRBESARTAN/HCTZ. Exposure to sunlight should be minimized until you know how you respond.

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

Hypersensitivity reactions (angioedema, urticarial, anaphylactic reactions including anaphylactic shock) have been reported.

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

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/HCTZ:

- Adrenocorticotropic hormone (ACTH) used to treat West Syndrome.
- Alcohol, barbiturates (sleeping pills), or narcotics (strong pain medications). They may cause low blood pressure and dizziness when you go from lying or sitting to standing up.
- Amphotericin B, an antifungal drug.
- Anticancer drugs, including cyclophosphamide and methotrexate.
- Antidepressants, in particular selective serotonin reuptake inhibitors (SSRIs), including citalopram, escitalopram, and sertraline.
- Antidiabetic drugs, including insulin and oral medicines.
- Beta-blockers (medications for heart disease)
- Bile acid resins used to lower cholesterol.
- Blood pressure-lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. RASILEZ[®]), or angiotensin converting enzyme (ACE) inhibitors.
- Calcium or vitamin D supplements.
- Corticosteroids used to treat joint pain and swelling and other conditions.
- Digoxin, a heart medication.
- Drugs that slow down or speed up bowel function, including atropine, metoclopramide, and domperidone.
- Drugs used to treat epilepsy, including carbamazepine and topiramate.
- Gout medications, including allopurinol and probenecid.
- Hyperglycemic agent, such as diazoxide.
- Lithium used to treat bipolar disease.

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- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Potassium-sparing diuretics, potassium supplements or potassium-containing salt substitutes.
- Pressor amines such as norepinephrine.
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurarine.
- Warfarin.

PROPER USE OF THIS MEDICATION

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

IRBESARTAN/HCTZ can be taken with or without food but it should be taken the same way each day. If IRBESARTAN/HCTZ causes upset stomach, take it with food or milk.

Usual Adult dose:

Patients should be individually titrated for each component separately.

Usual maintenance dose is: 1 tablet daily.

Overdose:

If you think you have taken too much IRBESARTAN/HCTZ, 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- back or leg pain, muscle cramps, spasms and pain, weakness, restlessness
- dizziness, pins and needles in your fingers, headache and fatigue
- constipation, diarrhea, nausea, vomiting, decreased appetite, upset stomach, enlargement of the glands in your mouth
- bleeding under the skin, rash, red patches on the skin
- drowsiness, insomnia
- reduced libido

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

IRBESARTAN/HCTZ 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 call your doctor or pharmacist
		Only if severe	In all cases	
Common	Low Blood Pressure: Dizziness, fainting, lightheadedness. May occur when you go from lying or sitting to standing up.	✓		
	Edema: swelling of hands, ankles or feet		✓	
	Tachycardia: increased heart beats		✓	
	Decreased or increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell		✓	
	<i>Non-melanoma skin cancer:</i> lump or discoloured patch on the skin that stays after a few weeks and slowly changes. Cancerous lumps are red/pink and firm and sometimes turn into ulcers. Cancerous patches are usually flat and scaly changes. Cancerous lumps are red/pink and firm and sometimes turn into ulcers. Cancerous patches are usually flat and scaly.		✓	
Uncommon	Allergic reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
	Kidney disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		✓	
	Liver disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
	Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
	Increased blood sugar: frequent urination, thirst and hunger	✓		
Rare	Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine		✓	

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	Decreased white blood cells: infections, fatigue, fever, aches, pains and flu-like symptoms		✓	
	Decreased platelets: bruising, bleeding, fatigue and weakness		✓	
Very Rare	Toxic epidermal necrolysis: severe skin peeling, especially in mouth and eyes			✓
Unknown	Eye disorders: - Myopia: sudden near sightedness or blurred vision - Glaucoma: increased pressure in your eyes, eye pain			✓
	Anemia: fatigue, loss of energy, weakness, shortness of breath		✓	
	Inflammation of the Pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		✓	
	Hypersensitivity Reaction: Anaphylactic reaction, anaphylactic shock			✓
	Skin reaction: psoriasis, photosensitivity		✓	
	Thrombocytopenia: decrease platelet count (thrombocytopenic purpura)		✓	

This is not a complete list of side effects. For any unexpected effects while taking IRBESARTAN/HCTZ, 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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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 at room temperature (15 to 30°C).

Keep out of reach and sight of children.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Sanis Health Inc. at:

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

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