

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr IRBESARTAN HCT

Irbesartan hydrochlorothiazide Tablets

Read this carefully before you start taking IRBESARTAN HCT 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 IRBESARTAN HCT.

Serious Warnings and Precautions

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

What is IRBESARTAN HCT used for?

- IRBESARTAN HCT is used in adults to lower high blood pressure.

How does IRBESARTAN HCT work?

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

- Irbesartan is an angiotensin receptor blocker (ARB). It lowers blood pressure.
- Hydrochlorothiazide is a diuretic or “water pill” that increases urination. This also helps to lower blood pressure.

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

What are the ingredients in IRBESARTAN HCT:

Medicinal ingredients: Irbesartan and hydrochlorothiazide.

Non-medicinal ingredients: Croscarmellose sodium, hydroxypropylcellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, silica colloidal anhydrous, polyethylene glycol, titanium dioxide, talc.

IRBESARTAN HCT 150/12.5 mg and 300/12.5 mg also contain ferric oxide red and ferric oxide yellow.

IRBESARTAN HCT 300 mg/25 mg also contains ferric oxide red and ferric oxide black.

IRBESARTAN HCT comes in the following dosage forms:

IRBESARTAN HCT tablets are oval biconvex film-coated tablet, available in three dosage strengths:

150 mg/12.5 mg is apricot, debossed with 150H on one side

300 mg/12.5 mg is apricot, debossed with 300H on one side

300 mg/25 mg is dark pink, debossed with 300 on one side and 25H on other side

Do not use IRBESARTAN HCT if you:

- are allergic to irbesartan or hydrochlorothiazide or to any non-medicinal ingredients 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 healthcare professional 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 HCT during pregnancy can cause injury and even death to your baby.
- are breast-feeding. IRBESARTAN HCT passes into breast milk.
- have one of the following rare hereditary diseases:
 - o Galactose intolerance
 - o Lapp lactase deficiency
 - o Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in IRBESARTAN HCT

IRBESARTAN HCT 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 IRBESARTAN HCT. 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.
- are allergic to penicillin.
- 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. IRBESARTAN HCT may cause low blood sugar levels.
- 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 HCT is not recommended.
- are taking an angiotensin converting enzyme (ACE) inhibitors. The combination with IRBESARTAN HCT is not recommended.
- are taking a medicine that contains lithium. The combination with IRBESARTAN HCT is not recommended.
- 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.

Other warnings you should know about:

Risk of skin cancer:

- IRBESARTAN HCT 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 HCT for many years (more than 3) or at a high dose.
- While taking IRBESARTAN HCT:
 - o 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.
 - o You may become sensitive to the sun
 - o 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 healthcare professional immediately if you become 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 treatment.

Sudden Eye Disorders:

- IRBESARTAN HCT contains hydrochlorothiazide. Treatment with hydrochlorothiazide may increase the risk of developing sudden eye problems.
- **Myopia:** sudden nearsightedness or blurred vision.
- **Glaucoma:** an increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss.
- **Choroidal effusion:** abnormal buildup of liquid in your eye that may result in vision changes

If your vision changes, stop taking IRBESARTAN HCT and seek immediate medical help. These eye disorders are related and can develop within hours to weeks of starting IRBESARTAN HCT. If you have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this. Talk to your healthcare professional immediately if you develop any eye problems while taking IRBESARTAN HCT.

Before surgery and general anesthesia (even at the dentist's office), tell the doctor or dentist that you are taking IRBESARTAN HCT, 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 IRBESARTAN HCT 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 IRBESARTAN HCT. 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 IRBESARTAN HCT:

- 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, such as repaglinide.
- 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 agents, such as diazoxide.
- Lithium used to treat bipolar disease.
- 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.

How to take IRBESARTAN HCT:

- Take IRBESARTAN HCT every day exactly as prescribed.
- It is recommended to take your dose at about the same time every day.
- IRBESARTAN HCT can be taken with or without food but it should be taken the same way each day.
- If IRBESARTAN HCT causes upset stomach, take it with food or milk.

Usual Dose:

1 tablet once daily.

Overdose:

If you think you, or a person you are caring for, have taken too much IRBESARTAN HCT, 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 IRBESARTAN HCT?

These are not all the possible side effects you may feel when taking IRBESARTAN HCT. If you experience any side effects not listed here, contact your healthcare professional.

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
- rash, red patches on the skin
- drowsiness, insomnia
- reduced libido
- lightheadedness
- ringing in the ears

IRBESARTAN HCT 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	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: fast heart beat		✓	
	Decreased or increased levels of potassium in the blood: irregular heartbeats, muscle weakness, generally feeling unwell		✓	

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	
	Non-melanoma skin cancer: 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.		✓	
UNCOMMON	Allergic reaction and angioedema: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
	Kidney problems: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		✓	
	Liver problems: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
	High blood sugar: frequent urination, thirst, and hunger	✓		
RARE	Rhabdomyolysis : muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine		✓	
	Decreased white blood cells: infections, fatigue, fever, aches, pains, and flu-like symptoms		✓	
	Decreased platelets: bruising, bleeding, fatigue, weakness, small purple or red dots under the skin		✓	
VERY RARE	Serious skin reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis): any combination of itchy skin rash, redness, blistering and peeling of the skin and/or of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or joint pain, yellowing of the skin or eyes, dark urine			✓
UNKNOWN	Eye disorders: - Myopia: sudden near sightedness or blurred vision - Glaucoma: increased pressure in your eyes, eye pain - Choroidal effusion: blind spots, eye pain, blurred vision			✓
	Anemia (decreased number of red blood cells): fatigue, loss of energy, looking pale, weakness, shortness of breath		✓	
	Inflammation of the pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		✓	
	Skin problems: psoriasis, increased skin sensitivity to sunlight		✓	

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	
	Low blood sugar: sweating, weakness, hunger, dizziness, trembling, headache		✓

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

Storage:

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

Keep out of reach and sight of children.

If you want more information about IRBESARTAN HCT:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer 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.sivem.ca), or by calling the manufacturer, at 1-855-788-3153.

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