

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrAVALIDE®

Irbesartan and hydrochlorothiazide Tablets

Read this carefully before you start taking **AVALIDE** 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 **AVALIDE**.

Serious Warnings and Precautions

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

What is AVALIDE used for?

- AVALIDE is used in adults to lower high blood pressure.

How does AVALIDE work?

AVALIDE 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 AVALIDE regularly even if you feel fine.

What are the ingredients in AVALIDE?

Medicinal ingredients: Irbesartan and hydrochlorothiazide

Non-medicinal ingredients: Carnauba wax, croscarmellose sodium, ferric oxide red, ferric oxide yellow, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, titanium dioxide

AVALIDE comes in the following dosage forms:

Tablets, in two strengths:

irbesartan/hydrochlorothiazide: 150 mg /12.5 mg

irbesartan/hydrochlorothiazide: 300 mg /12.5 mg

Do not use AVALIDE 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 AVALIDE during pregnancy can cause injury and even death to your baby.
- are breast-feeding. AVALIDE 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 AVALIDE.

AVALIDE 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 AVALIDE®. 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. AVALIDE 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 AVALIDE is not recommended.
- are taking an angiotensin converting enzyme (ACE) inhibitors. The combination with AVALIDE is not recommended.
- are taking a medicine that contains lithium. The combination with AVALIDE 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.
- have had breathing or lung problems (including inflammation or fluid in the lungs) in the past following the use of medication containing hydrochlorothiazide or certain diuretics (i.e., “water

pills”). If you develop any severe shortness of breath or difficulty breathing after taking AVALIDE, stop the medication and seek medical attention immediately.

Other warnings you should know about:

Risk of skin cancer:

- AVALIDE contains hydrochlorothiazide. Treatment with hydrochlorothiazide may increase the risk of developing non-melanoma skin cancer. The risk is higher if you have been taking AVALIDE for many years (more than 3) or at a high dose.
- While taking AVALIDE:
 - 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.
 - You may become sensitive to the sun.
 - 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:

- AVALIDE 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 AVALIDE and seek immediate medical help. These eye disorders are related and can develop within hours to weeks of starting AVALIDE. 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 AVALIDE.

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

- Adrenocorticotrophic 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 tubocurare.
- Warfarin.

How to take AVALIDE:

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

These are not all the possible side effects you may feel when taking AVALIDE. 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

AVALIDE 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. | X | | |
| Edema: swelling of hands, ankles or feet | | X | |
| Tachycardia: fast heart beat | | X | |
| Decreased or 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 |
| 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 | | X | |

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|---|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| 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 | | | X |
| Kidney problems: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue | | X | |
| Liver problems: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite | | X | |
| High blood sugar: frequent urination, thirst, and hunger | X | | |
| RARE | | | |
| Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine | | X | |
| Decreased white blood cells: infections, fatigue, fever, aches, pains, and flu-like symptoms | | X | |
| Decreased platelets: bruising, bleeding, fatigue, weakness, small purple or red dots under the skin | | X | |
| VERY RARE | | | |
| Acute respiratory distress (inflammation of lung tissue or excess fluid in the lungs): severe shortness of breath or difficulty breathing, fever, weakness, and confusion. | | | X |
| Serious skin reactions (Stevens-Johnson Syndrome, Toxic | | | X |

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|---|--------------------------------------|--------------|---|
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| | Only if severe | In all cases | |
| 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 FREQUENCY | | | |
| 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 | | | X |
| Anemia (decreased number of red blood cells): fatigue, loss of energy, looking pale, weakness, shortness of breath | | X | |
| Inflammation of the pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting | | X | |
| Skin problems: psoriasis, increased skin sensitivity to sunlight | | X | |
| Low blood sugar: sweating, weakness, hunger, dizziness, trembling, headache | | | 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, 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 AVALIDE at room temperature (15 to 30°C).

Keep out of reach and sight of children.

If you want more information about AVALIDE:

- 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: [move\(https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html\)](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.

Last Revised January 30, 2023

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