

PART III: CONSUMER INFORMATION

HYZAAR[®]
and
HYZAAR[®] DS

losartan potassium and hydrochlorothiazide tablets

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

ABOUT THIS MEDICATION

What the medication is used for:

HYZAAR[®] and HYZAAR[®] DS lowers high blood pressure.

What it does:

HYZAAR[®] and HYZAAR[®] DS contains a combination of 2 drugs, losartan component and hydrochlorothiazide:

- losartan component 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 HYZAAR[®] and HYZAAR[®] DS regularly even if you feel fine.

When it should not be used:

Do not take HYZAAR[®] and HYZAAR[®] DS if you:

- are allergic to losartan potassium and hydrochlorothiazide or any of the 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. Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.
- Have been diagnosed with hereditary angioedema: an increased risk of getting an allergic reaction that is passed down through families. This can be triggered by different factors, such as surgery, flu, or dental procedures.
- have difficulty urinating or produce no urine.
- are already taking a blood pressure-lowering medicine that contains aliskiren (such as Rasilez) and you have diabetes or kidney disease.

- are pregnant or intend to become pregnant. Taking HYZAAR[®] and HYZAAR[®] DS during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. HYZAAR[®] and HYZAAR[®] DS passes into breast milk.
- Have one of the following rare hereditary diseases since lactose is a non-medicinal ingredient in HYZAAR[®] and HYZAAR[®] DS:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in HYZAAR[®] and HYZAAR[®] DS.

What the medicinal ingredients are:

Losartan potassium and hydrochlorothiazide

What the non-medicinal ingredients are:

HYZAAR[®] 50 mg/12.5 mg, HYZAAR[®] 100 mg/12.5 mg and HYZAAR[®] DS 100 mg/25 mg contain the following non-medicinal ingredients: hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, titanium dioxide and may contain carnauba wax. HYZAAR[®] 50 mg/12.5 mg and HYZAAR[®] DS 100 mg/25 mg also contain quinoline yellow aluminum lake or D & C Yellow No. 10 aluminum lake. HYZAAR[®] 50 mg/12.5 mg contains 4.24 mg (<1 mmol) of potassium and HYZAAR[®] 100 mg/12.5 mg and HYZAAR[®] DS 100 mg/25 mg contain 8.48 mg (<1 mmol) of potassium, as losartan potassium.

Although HYZAAR[®] 50 mg/12.5 mg, HYZAAR[®] 100 mg/12.5 mg and HYZAAR[®] DS 100 mg/25 mg contain a very small amount of potassium, they cannot replace potassium supplements. If your physician has prescribed potassium supplements, continue to follow his advice.

What dosage forms it comes in:

Tablets HYZAAR[®] 50 mg/12.5 mg, HYZAAR[®] 100 mg/12.5 mg and HYZAAR[®] DS 100 mg/25 mg

WARNINGS AND PRECAUTIONS

Serious Warning and Precautions – Pregnancy
HYZAAR[®] and HYZAAR[®] DS should not be used during pregnancy. If you discover that you are pregnant while taking HYZAAR[®] and HYZAAR[®] DS, stop the medication and contact your doctor, nurse, or pharmacist as soon as possible.

BEFORE you use HYZAAR[®] and HYZAAR[®] DS, talk to your doctor, nurse or pharmacist if you:

- are allergic to any drug used to lower blood pressure, including angiotensin converting enzyme (ACE) inhibitors, or penicillin.

- have narrowing of an artery or a heart valve.
- have had a heart attack or stroke.
- have recently received or are planning to get allergy shots for bee or wasp stings.
- have heart failure.
- have diabetes, liver or kidney disease.
- you are taking a medicine that contains aliskiren, such as Rasilez, used to lower high blood pressure. The combination with HYZAAR® is not recommended.
- you are taking an angiotensin-converting-enzyme inhibitor (ACEI).
- have lupus or gout.
- 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”).
- are on a low-salt diet.
- are less than 18 years old.
- are receiving gold (sodium aurothiomalate) injections.
- have to undergo any kind of surgery and general anesthesia (even at the dentist’s office). Tell the physician or dentist that you are taking HYZAAR®, as there may be a sudden fall in blood pressure associated with general anesthesia.
- are hypersensitive to this drug or to any ingredient in the formulation.
- are taking other drugs that may increase serum potassium (e.g. trimethoprim-containing products).
- 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.

Hydrochlorothiazide in HYZAAR® and HYZAAR® DS 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 HYZAAR® and HYZAAR® DS.

Risk of skin cancer:

HYZAAR® and HYZAAR® DS contains hydrochlorothiazide. Treatment with hydrochlorothiazide may increase the risk of developing non-melanoma skin cancer. The risk is higher if you have been taking HYZAAR® and HYZAAR® DS for many years (more than 3) or at a high dose.

While taking HYZAAR® and HYZAAR® DS

- 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 of skin to sun and avoid 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.

You may become sensitive to the sun while taking HYZAAR® and HYZAAR® DS. Exposure to sunlight should be minimized.

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

Taking HYZAAR® during pregnancy can cause injury and even death to your baby. This medicine should not be used during pregnancy. If you are planning to become pregnant while taking HYZAAR®, contact immediately your physician.

It is possible that HYZAAR® passes into breast milk. You should discuss with your physician about taking HYZAAR® while breastfeeding.

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 HYZAAR® and HYZAAR® DS:

- 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.
- Amphoterecin 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.
- Bile acid resins used to lower cholesterol.
- Calcium or vitamin D supplements.
- Corticosteroids used to treat joint pain and swelling.
- 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.
- Glycyrrhizin (found in liquorice).
- Lithium used to treat bipolar disease.
- Medicines may cause high blood pressure (adrenaline).
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Other blood pressure lowering drugs. When taken in combination with HYZAAR® and HYZAAR® DS, they may cause excessively low blood pressure.
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurare.
- Sympathomimetics which may be found in some decongestants, cough/cold, hay fever, sinus medicines.
- Potassium supplements, salt substitutes containing potassium or other drugs that may increase serum potassium (e.g., trimethoprim-containing products)

PROPER USE OF THIS MEDICATION

Take HYZAAR® and HYZAAR® DS exactly as prescribed. It is recommended to take your dose at about the same time everyday.

HYZAAR® and HYZAAR® DS can be taken with or without food. If HYZAAR® and HYZAAR® DS causes upset stomach, take it with food or milk.

Usual Adult dose:

- **Take HYZAAR® every day exactly as your doctor has instructed.** It is important to continue taking HYZAAR® for as long as your physician prescribes it in order to maintain smooth control of your blood pressure.
- The usual dose of HYZAAR® for most patients with high blood pressure is 1 tablet of HYZAAR 50 mg/12.5 mg per day to control blood pressure over the 24-hour period.

Overdose:

If you think you have taken too much HYZAAR® and HYZAAR® DS, 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, joint pain
- Dizziness, pins and needles in your fingers, headache
- 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
- Erectile dysfunction/impotence
- Reduced libido
- Increased sensitivity to the sun
- A feeling of dizziness or lightheadedness due to a sudden drop in blood pressure when standing up quickly
- Cramping
- Fatigue
- Hives, itch and bruising
- Taste alteration
- Seeing more of the colour yellow in your vision, or temporary blurred vision
- Dry cough, nasal congestion and upper respiratory infections
- Fever

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

HYZAAR® and HYZAAR® DS 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

Symptoms / Effects	Talk with your physician or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Uncommon/ rare			
Low Blood Pressure: dizziness, fainting, lightheadedness may occur when you go from lying or sitting to standing up			√
Allergic Reaction: skin rash, skin eruption or other effect on the skin or eyes, swelling of the face, lips, tongue or throat, accompanied by difficulty in swallowing, breathing, or speaking (signs of angioedema)			√
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, sugar in the urine		√	

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

Symptoms / Effects	Talk with your physician or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Common			
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.		√	
Electrolyte imbalance including decreased or increased levels of potassium in the blood or decreased levels of sodium in the blood: irregular heartbeats, muscle weakness, generally feeling unwell, drowsiness, muscle pain or cramps, lack of energy, confusion, muscle twitching		√	
Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue	√	√ (renal failure)	
Chest pain		√	
Swelling of the hands or ankles	√		
Red tender, hot, swollen joint (gout), high uric acid levels in the blood (hyperuricemia)	√ (hyperuricemia)	√ (gout)	
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		√	
Unknown			
Decreased Platelets: bruising, bleeding, fatigue and weakness		√	
Toxic Epidermal Necrolysis: severe skin peeling, especially in mouth and eyes			√
Eye disorders: - Myopia: sudden near sightedness or blurred vision - Glaucoma: increased pressure in your eyes, eye pain			√
Uncommon			
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			√
Racing or irregular heart rate	√		

This is not a complete list of side effects. For any unexpected effects while taking HYZAAR® and HYZAAR® DS, contact your doctor, nurse, or pharmacist.

HOW TO STORE IT

Store HYZAAR® and HYZAAR® DS at room temperature (15°C–30°C). Keep container tightly closed. Protect from light.

Keep all medicines out of the reach of children.

REPORTING SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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.

MORE INFORMATION

If you want more information about HYZAAR® and HYZAAR® DS:

- 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](#) or Organon Canada website www.organon.ca or by calling Organon Canada at 1-844-820-5468.

This leaflet was prepared by Organon Canada Inc.

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