

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrHYZAAR® and PrHYZAAR® DS

losartan potassium and hydrochlorothiazide tablets, USP

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 this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **HYZAAR** and **HYZAAR DS**.

Serious Warnings and Precautions

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

What are HYZAAR and HYZAAR DS used for?

HYZAAR and HYZAAR DS are used in adults to lower high blood pressure.

How do HYZAAR and HYZAAR DS work?

HYZAAR and HYZAAR DS contains a combination of 2 drugs, losartan and hydrochlorothiazide:

- losartan 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 HYZAAR and HYZAAR DS regularly even if you feel fine.

What are the ingredients in HYZAAR and HYZAAR DS?

Medicinal ingredients: losartan potassium and hydrochlorothiazide.

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.

Although HYZAAR and HYZAAR DS contain potassium, this amount is too small to replace potassium supplements. If your doctor has prescribed potassium supplements, continue to follow their advice.

HYZAAR and HYZAAR DS come in the following dosage forms:

HYZAAR tablets; 50 mg/12.5 mg, 100 mg/12.5 mg

HYZAAR DS tablets; 100 mg/25 mg

Do not use HYZAAR or HYZAAR DS if:

- you are allergic to losartan potassium and hydrochlorothiazide or any of the non-medicinal ingredients in the formulation.
- you are allergic to any sulfonamide-derived drugs (sulfa drugs); most of them have a medicinal ingredient that ends in “-MIDE”.
- you have difficulty urinating or produce no urine.
- you are already taking a blood pressure-lowering medicine that contains aliskiren (such as Rasilez) and you have diabetes or kidney disease.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take HYZAAR or HYZAAR DS. Talk about any health conditions or problems you may have, including if you:

- are allergic to any drug used to lower blood pressure, including angiotensin converting enzyme (ACE) inhibitors, or penicillin.
- are taking an ACE inhibitor.
- 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.
- 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, a potassium-sparing diuretic (a specific kind of “water pill”), or other drugs that may increase potassium levels (such as trimethoprim-containing products).
- are on a low-salt diet.
- 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.
- are pregnant, planning to become pregnant or think you are pregnant.
- are breastfeeding or plan to breastfeed.
- have had breathing or lung problems (including inflammation or fluid in the lungs) in the past following the use of medication containing hydrochlorothiazide. If you experience any severe shortness of breath or difficulty breathing after taking HYZAAR or HYZAAR DS, stop the medication and seek medical attention immediately.

Other warnings you should know about:

Use of anesthesia: If you are about to have a surgery or dental procedure with anesthesia, be sure to tell your healthcare professional that you are taking HYZAAR or HYZAAR DS.

Risk of skin cancer: HYZAAR and HYZAAR DS contain 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 healthcare professional 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.

Eye problems: Hydrochlorothiazide in HYZAAR and HYZAAR DS can cause sudden eye disorders:

- **Choroidal effusion:** an abnormal building of liquid in your eye that may result in vision changes.
- **Myopia:** sudden nearsightedness or blurred vision.
- **Glaucoma:** an increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss.

If your vision changes, stop taking HYZAAR or HYZAAR DS and seek immediate medical help. These eye disorders are related and can develop within hours to weeks of starting HYZAAR or HYZAAR DS.

Testing and check-ups: During your treatment with HYZAAR and HYZAAR DS, your healthcare professional may monitor:

- Your kidney function.
- Your blood pressure.
- The amount of electrolytes in your blood (such as potassium, sodium, calcium).
- Your liver function

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 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.

Serious Drug Interactions

- Aliskiren-containing drugs if you have diabetes or kidney disease.

The following may also interact with HYZAAR and HYZAAR DS:

- Other medications used to lower blood pressure, such as diuretics (“water pills”).
- Adrenocorticotrophic hormone (ACTH), which may be used to treat diseases such as nephrotic syndrome or collagen diseases and in diagnostic tests.
- 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 medications, such as cyclophosphamide and methotrexate.
- Antidepressants, in particular selective serotonin reuptake inhibitors (SSRIs), including citalopram, escitalopram, and sertraline.
- Antidiabetic medications, such as insulin and oral medicines.
- Bile acid resins used to lower cholesterol such as cholestyramine.

- Calcium or vitamin D supplements.
- Corticosteroids used to treat joint pain and swelling.
- Digoxin, a heart medication.
- Medications that slow down or speed up bowel function, such as atropine, metoclopramide, and domperidone.
- Medications used to treat epilepsy, such as carbamazepine and topiramate.
- Glycyrrhizin (found in liquorice).
- Gout medications, such as allopurinol and probenecid.
- Grapefruit juice (which should be avoided while taking HYZAAR or HYZAAR DS).
- Lithium used to treat bipolar disease.
- Medicines may cause high blood pressure (adrenaline).
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling such as ibuprofen, naproxen, acetylsalicylic acid and celecoxib.
- Skeletal muscle relaxants used to relieve muscle spasms, such as 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).

How to take HYZAAR and HYZAAR DS:

- 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, but it should be taken the same way each day. If HYZAAR and HYZAAR DS causes upset stomach, take it with food or milk.

Usual dose:

Your healthcare professional has decided the best dose for you. The usual dose is 1 tablet of HYZAAR or HYZAAR DS once daily.

The maximum dose is 1 tablet of HYZAAR DS (100 mg/25 mg) once daily.

Overdose:

If you think you, or a person you are caring for, have taken too much HYZAAR or HYZAAR DS, 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 one at the usual time. Do not double the dose.

What are possible side effects from using HYZAAR and HYZAAR DS?

These are not all the possible side effects you may have when taking HYZAAR and HYZAAR DS. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- constipation
- decreased appetite

- diarrhea
- enlargement of the glands in your mouth
- nausea
- upset stomach
- vomiting
- cramping
- seeing more of the colour yellow in your vision
- temporary blurred vision
- fatigue
- fever
- back or leg pain
- joint pain
- muscle cramps
- restlessness
- spasms and pain
- weakness
- dizziness
- headache
- pins and needles in your fingers
- change in taste
- erectile dysfunction/impotence
- reduced libido
- dry cough
- nasal congestion
- upper respiratory infections
- bleeding under the skin
- rash
- red patches on the skin
- hives
- itch
- bruising
- increased sensitivity to the sun
- a feeling of dizziness or lightheadedness due to a sudden drop in blood pressure when standing up quickly

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 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			
Chest pain		√	
Edema: swelling of the hands or ankles	√		

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	
Electrolyte imbalance: confusion, drowsiness, generally feeling unwell, irregular heartbeats, lack of energy, muscle pain or cramps, muscle twitching, muscle weakness		√	
Gout: red, tender, hot, swollen joints, fever, generally feeling unwell, fast heart rate		√	
Kidney Disorder: change in frequency of urination, fatigue, nausea, swelling of extremities, vomiting		√	
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: difficulty breathing or swallowing, hives, skin rash and swelling of the face, lips, throat or tongue			√
Anemia (decreased number of red blood cells): fatigue, loss of energy, shortness of breath, weakness		√	
High blood sugar: frequent urination, thirst, and hunger, sugar in the urine		√	
Liver Disorder: abdominal pain, dark urine, nausea, loss of appetite, vomiting, yellowing of the skin or eyes			√
Low Blood Pressure: dizziness, fainting, light-headedness may occur when you go from lying or sitting to standing up			√
Pancreatitis (inflammation of the pancreas): abdominal pain that			√

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	
lasts and gets worse when you lie down, nausea, vomiting			
Tachycardia: Racing or irregular heart rate	√		
RARE			
Decreased White Blood Cells: aches, fatigue, fever, flu-like symptoms, infections, pains		√	
Rhabdomyolysis (breakdown of damaged muscle): dark brown urine, muscle pain that you cannot explain, muscle tenderness or weakness		√	
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			√
UNKNOWN FREQUENCY			
Decreased Platelets: bruising, bleeding, fatigue, weakness, small purple or red dots under the skin		√	
Eye disorders: - Myopia: sudden near sightedness or blurred vision - Glaucoma: increased pressure in your eyes, eye pain, decrease in vision - Choroidal effusion (buildup of liquid in your eye): blind spots, eye pain, blurred vision			√
Toxic Epidermal Necrolysis (a severe skin reaction): redness, blistering an/or severe skin peeling, especially in mouth and eyes			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 HYZAAR and HYZAAR DS at room temperature (15°C – 30°C). Keep container tightly closed. Protect from light.
- Keep out of reach and sight of children.

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 Patient Medication 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.organon.ca, or by calling 1-844-820-5468.

This leaflet was prepared by Organon Canada Inc.

Last Revised January 31, 2023

* N.V. Organon. Used under license.

© 2023 Organon group of companies. All rights reserved