

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrDIOVAN®

valsartan tablets

Read this carefully before you start taking **DIOVAN®** 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 **DIOVAN**.

Serious Warnings and Precautions

- **Pregnancy:** Angiotensin receptor blockers (ARBs), such as DIOVAN, can cause harm or even death to your unborn baby. Therefore, DIOVAN should not be taken during pregnancy. If you become pregnant or think you are pregnant, stop taking DIOVAN right away and tell your healthcare professional.

What is DIOVAN used for?

DIOVAN is used in adults:

- to treat mild to moderate high blood pressure. It may be given alone or in combination with diuretics (i.e., water pills).
- to reduce the risk of death after a heart attack when an angiotensin-converting enzyme (ACE) inhibitor, considered part of standard therapy for this condition, is not appropriate. DIOVAN is given to patients who are in a stable condition but have signs or symptoms of heart problems.
- with chronic heart failure when they are unable to tolerate the standard treatment with medicines called ACE inhibitors.

How does DIOVAN work?

DIOVAN is an angiotensin receptor blocker (ARB) that helps relax blood vessels. This makes it easier for your heart to pump blood around your body. This helps to lower your blood pressure.

What are the ingredients in DIOVAN?

Medicinal ingredients: Valsartan

Non-medicinal ingredients: Black iron oxide, colloidal silicon dioxide, crospovidone, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, red iron oxide, and titanium dioxide.

In addition, the 40 mg, 160 mg and 320 mg tablets also contain yellow iron oxide.

DIOVAN comes in the following dosage forms:

Tablets: 40 mg, 80 mg, 160 mg and 320 mg

Do not use DIOVAN if:

- you are allergic to valsartan or to any other ingredients in DIOVAN.
- you are pregnant or planning to become pregnant.
- you are breastfeeding or planning to breastfeed.
- you are taking medicines that contain aliskiren (such as RASILEZ) that help lower blood pressure **and** you have diabetes or kidney disease.

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

- are taking other medicines, including:
 - medicines used to lower high blood pressure such as angiotensin-converting enzyme (ACE) inhibitors, diuretics (“water pills”) and medicines containing aliskiren;
 - medicines that increase the level of potassium in the blood such as a salt substitute that contains potassium, potassium supplements, potassium-sparing diuretics (a type of “water pill”), heparin (used to treat and prevent blood clots), etc.
- ever had an allergic reaction, which may involve swelling of the hands, feet, or ankles, face, lips, tongue, throat, or sudden difficulty breathing or swallowing (angioedema), when taking other medicines, including:
 - medicines used to treat high blood pressure such as ACE inhibitors and angiotensin receptor blockers (ARBs).
- have or have had heart problems (e.g., heart attack, heart failure, narrowing of an artery or a heart valve).
- have had problems that affect the blood flow and blood vessels in the brain (e.g., stroke).
- have diabetes.
- have kidney problems.
- are undergoing dialysis (a procedure to remove waste products and excess fluid from the blood when the kidneys stop working properly).
- are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- are on a low-salt diet.
- have liver problems.

Other warnings you should know about:

DIOVAN can cause the following:

- **Angioedema** (swelling of tissue under the skin): Treatment with DIOVAN can cause angioedema. This can be life-threatening. Your healthcare professional will monitor your health for signs of angioedema. If you notice swelling on your body or have difficulty swallowing or breathing, stop taking DIOVAN and tell your healthcare professional right away.

- **Hypotension** (low blood pressure): Treatment with DIOVAN can cause hypotension, in some cases even after the first dose. Patients who have heart failure or are taking DIOVAN after a heart attack are at a higher risk of experiencing low blood pressure. Your healthcare professional may monitor your health and adjust your dose as needed. Tell your healthcare professional, if you notice an increase in sweating, feel dehydrated, are vomiting, or have diarrhea.
- **Kidney problems:** Treatment DIOVAN can cause kidney problems resulting in decreased urine, progressive azotemia (high levels of nitrogen in the blood), kidney failure or even death. Your healthcare professional will closely monitor your kidneys before and during your treatment. They may decide to reduce or stop your treatment.

See the **Serious side effects and what to do about them table**, below, for more information on these and other serious side effects.

Driving and using machines: DIOVAN can decrease your blood pressure causing light-headedness, dizziness, and fainting. These can occur more often after your first dose, and when your dose is increased. Before you drive or do tasks that require special attention, wait until you know how you respond to DIOVAN.

Check-ups and testing: You may have regular visits with your healthcare professional, before, during and after your treatment. These tests may be used to monitor your health such as your kidney function, and blood pressure.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do not use DIOVAN if you take:

- medicines that contain aliskiren that are used to lower blood pressure and you have diabetes or kidney disease.

The following may interact with DIOVAN:

- other medicines used to lower high blood pressure such as ACE inhibitors, and ARBs.
- medicines known as diuretics (“water pill”) such as potassium-sparing diuretic and potassium-retaining diuretics (e.g., spironolactone, triamterene, or amiloride).
- medicines that increase the potassium in the blood such as a salt substitute that contains potassium, potassium supplements, and a potassium-sparing diuretic (a type of “water pill”).
- medicines used to treat and prevent blood clots such as heparin.
- non-steroidal anti-inflammatory drugs (NSAIDs) that are used to reduce pain and swelling such as ibuprofen, naproxen, celecoxib, indomethacin, and acetylsalicylic acid (aspirin).

- medicines used to treat bacterial infections such as trimethoprim-sulfamethoxazole and rifampin.
- medicines used to treat bipolar disorder such as lithium.
- medicines used to treat heart conditions such as digoxin.
- medicines used to suppress the immune system such as cyclosporine.
- medicines used to treat HIV/AIDS such as ritonavir.

How to take DIOVAN:

- Your healthcare professional will decide the dose and length of DIOVAN for you. They may start with a low dose and slowly adjust the dose as needed. Take DIOVAN exactly as prescribed by your healthcare professional.
- DIOVAN can be taken with or without food, but it should be taken the same way each day.
- It is recommended that you take your dose at about the same time everyday. If you take DIOVAN once a day, it should preferably be taken in the morning.
- Your healthcare professional will monitor your health throughout your treatment and may interrupt, reduce or stop your dose.
- If you take diuretics (i.e., “water pills”), your healthcare professional may ask you to temporarily stop taking them 2 or 3 days before you start your treatment with DIOVAN. They may also reduce their dose during your treatment. Furthermore, your healthcare professional may also prescribe you other medications depending on your condition. Follow their instructions carefully.

Usual dose:

To treat high blood pressure:

- The recommended initial dose is 80 mg once a day.
- Your dose may be adjusted as needed.
- The maximum daily dose is 320 mg.

To reduce the risk of death after a heart attack:

- The recommended starting dose is 20 mg twice a day.
- Your dose may be gradually increased to a target maintenance dose of 160 mg twice a day, as tolerated.

To treat chronic heart failure:

- The recommended starting dose is 40 mg twice a day.
- Your dose may be increased every two weeks to the highest dose you can tolerate.
- The maximum recommended dose is 160 mg twice a day.

Overdose:

Signs of an overdose with DIOVAN may include:

- low blood pressure, which can lead to shock (rapid breathing, pale skin, cold and sweaty skin).
- decreased consciousness.
- a rapid or slow heart rate.

If you think you, or a person you are caring for, have taken too much DIOVAN, 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, skip the missed dose and take your next dose at the usual time. Do not double the doses.

What are possible side effects from using DIOVAN?

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

Side effects may include:

- dizziness, difficulty in maintaining your balance while standing, fainting
- diarrhea, nausea, vomiting, indigestion
- chest pain, respiratory tract infection, runny or stuffy nose, cough, throat pain, fever, chills, body aches
- pain or swelling of the hands, arms, legs or feet
- itchy skin
- fatigue, lack of energy
- impotence, decreased sexual desire
- drowsiness, problems with sleeping
- headache
- back pain
- muscle pain or aches, weakness or inflammation
- joint pain
- nosebleed
- changes in taste

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			
Allergic reactions: Skin rash, skin eruption or other effect on the skin or eyes			✓

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	
Increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell		✓	
UNCOMMON			
Hypotension (low blood pressure): dizziness, fainting, light-headedness (may occur when you go from lying or sitting to standing up), blurred vision, nausea, vomiting, or fatigue	✓		
Angioedema/ Allergic reactions: swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, fever, wheezing, drop in blood pressure, or feeling sick to your stomach and throwing up			✓
Kidney problems: increased or decreased urination, nausea, vomiting, swelling of extremities, fatigue, fever, thirst, dry skin, irritability, dark urine, blood in the urine, rash, weight gain (from retaining fluid), loss of appetite, abnormal blood test results, or mental status changes (drowsiness, confusion, coma)		✓	
Liver problems: yellowing of the skin or eyes (jaundice), dark urine, abdominal pain or swelling, nausea, vomiting, loss of appetite or unusual tiredness		✓	
Rhabdomyolysis (breakdown of damaged muscle): muscle tenderness, weakness, red-		✓	

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	
brown (tea-coloured) urine			
Abdominal pain		✓	
Vasculitis (Inflammation of blood vessels): purplish-red spots, fever, itching	✓		
Decreased Platelets: bruising, unusual bleeding, fatigue and weakness		✓	
Anemia (decreased number of red blood cells): fatigue, loss of energy, weakness, shortness of breath, irregular heartbeats, or pale complexion		✓	
Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms		✓	
Palpitations: irregular heartbeats		✓	
UNKNOWN FREQUENCY			
Serious skin reactions: raised red or purple skin patches, possibly with blister or crust in the center, possibly swollen lips, mild itching or burning; blisters of different sizes; skin redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, can be accompanied with fever, chills, headache, cough, body aches or swollen glands			✓

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 at room temperature (15°C to 30°C). Protect from moisture and heat.
- Do not take DIOVAN past the expiry date shown on the pack.
- Keep out of the reach and sight of children.

If you want more information about DIOVAN:

- 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 <http://www.novartis.ca>, or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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