

CONSUMER INFORMATION

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 DIOVAN®. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about DIOVAN®.

ABOUT THIS MEDICATION

What the medication is used for:

High blood pressure (hypertension):

DIOVAN® lowers high blood pressure.

Following a heart attack (myocardial infarction):

DIOVAN® is used to treat people after a heart attack when an angiotensin-converting enzyme (ACE) inhibitor, considered part of standard therapy for this condition, is not appropriate.

Chronic heart failure:

DIOVAN® is used in patients with chronic heart failure, when they are unable to tolerate the standard treatment with medications called ACE inhibitors. There is no evidence that DIOVAN® provides added benefit when it is used with ACE inhibitors.

What it does:

DIOVAN is an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”.

This medicine does not cure your disease. It helps to control it. Therefore, it is important to continue taking DIOVAN regularly even if you feel fine.

When it should not be used:

Do not take DIOVAN® if you:

- Are allergic to **valsartan** or to any non-medicinal ingredient in the formulation.
- 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.
- Are taking a medicine that contains aliskiren (such as Rasilez) **and** you have diabetes or kidney disease.
- Are pregnant or intend to become pregnant. Taking

DIOVAN® during pregnancy can cause injury and even death to your baby.

- Are breastfeeding. It is possible that DIOVAN® passes into breast milk.

What the medicinal ingredient is:

Valsartan

What the nonmedicinal ingredients are:

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

Additional non medicinal ingredients for 40 mg, 160 mg and 320 mg tablets: yellow iron oxide.

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions - Pregnancy
DIOVAN® should not be used during pregnancy. If you discover that you are pregnant while taking DIOVAN®, stop the medication and contact your doctor, nurse, or pharmacist as soon as possible.

BEFORE you use DIOVAN® talk to your doctor, nurse or pharmacist if you:

- Have experienced an allergic reaction to any drug, including drugs used to lower blood pressure, such as angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARB).
- Have narrowing of an artery or a heart valve.
- Have had a heart attack or stroke.
- Have heart failure.
- Have diabetes, liver or kidney disease.
- 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 DIOVAN is not recommended.

- Are taking an angiotensin converting enzyme (ACE) inhibitor.
- Are less than 18 years old,

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

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 DIOVAN[®]:

- Agents increasing serum potassium, such as 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.
- Lithium, a medicine used to treat some types of psychiatric illness such as bipolar disease.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Other blood pressure lowering drugs, including diuretics (“water pills”), ACE inhibitors or aliskiren.
- Rifampin an antibiotic
- cyclosporine a drug used to protect against transplant rejection
- ritonavir a antiretroviral drug used to treat HIV/AIDS infection

PROPER USE OF THIS MEDICATION

Take DIOVAN[®] exactly as prescribed. Swallow DIOVAN[®] tablets with a glass of water. It is recommended to take your dose at about the same time everyday preferably in the morning. You can take DIOVAN[®] with or without food, but it should be taken the same way each day. Do not exceed the recommended dose.

Usual Adult Dose:

High blood pressure (hypertension):

Recommended Initial dose: 80 mg once a day. Dose should be increased gradually.

Maximum dose: 320 mg a day

Following a heart attack (myocardial infarction):

Recommended starting dose: 20 mg twice a day

Dose can be increased gradually.

Target maintenance dose: 160 mg twice a day

Chronic heart failure:

Recommended starting dose: 40 mg twice a day. Dose should be increased gradually.

Maximum dose: 160 mg twice a day

Overdose:

If you think you have taken too much DIOVAN[®] 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:

- Dizziness, light headedness,
- drowsiness,
- rash ,
- diarrhea, vomiting, nausea,
- headache,
- back or leg pain, muscle cramps,
- Muscle pain , muscle weakness,
- Unusual tiredness, weakness,
- Cough,
- Impotence,
- Nose bleed
- Blistering skin (sign of dermatitis bullous)

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

DIOVAN[®] 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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Allergic reactions: Skin rash, skin eruption or other effect on the skin or eyes			✓
	Increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell		✓	
Uncommon	Low blood pressure (hypotension): dizziness, fainting, lightheadedness May occur when you go from lying or sitting to standing up	✓		
	Angioedema/ Allergic reactions: rash, hives, swelling of the lips, face or neck, tongue or throat accompanied by difficulty in breathing, swallowing or speaking,			✓

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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
	Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		✓	
	Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
	Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine.		✓	
	Abdominal pain		✓	
	Cardiac failure: breathlessness, difficulty breathing when lying down, swelling of the feet or legs		✓	

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

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Vasculitis: Inflammation of blood vessels purplish-red spots, fever, itching	✓		
Decreased Platelets: bruising, unusual bleeding, fatigue and weakness		✓	
Anemia: fatigue, loss of energy, weakness, shortness of breath		✓	
Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms, sore throat or mouth ulcers		✓	
Insomnia	✓		
Flu like symptoms, joint pain, pharyngitis, inflammation of sinuses, runny or stuffy nose, swollen hands, ankles or feet, upper respiratory tract infection, viral infection	✓		

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

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Palpitations: irregular heartbeats		✓	
Unknown Change in libido	✓		
Unknown Blistering skin reactions with symptoms such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling and fever			✓

This is not a complete list of side effects. For any unexpected effects while taking DIOVAN[®], contact your doctor, nurse or pharmacist.

HOW TO STORE IT

Do not use DIOVAN[®] past the expiry date shown on the pack.

Store your DIOVAN[®] tablets in a dry place at room temperature (15 to 30°C).

Keep this medicine out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada

Vigilance Program

Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

Canada Inc.

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MORE INFORMATION

Please consult your doctor or pharmacist with any questions or concerns you may have regarding your individual condition.

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.novartis.ca>

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at:
Novartis Pharmaceuticals Canada Inc.
385 Bouchard Blvd.
Dorval, Quebec,
H9S 1A9
1-800-363-8883

This leaflet was prepared by Novartis Pharmaceuticals