

PART III: CONSUMER INFORMATION

PrDIOVAN-HCT® valsartan and hydrochlorothiazide tablets

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

ABOUT THIS MEDICATION

What the medication is used for:

DIOVAN-HCT lowers high blood pressure.

High blood pressure increases the workload of the heart and arteries. If this condition continues for a long time, damage to the blood vessels of the brain, heart, and kidneys can occur, and may eventually result in a stroke, heart failure or kidney failure. High blood pressure also increases the risk of heart attacks. Reducing your blood pressure decreases your risk of developing these illnesses.

What it does:

DIOVAN-HCT contains a combination of 2 drugs, valsartan and hydrochlorothiazide:

- Valsartan is an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”. It lowers blood pressure. DIOVAN-HCT does this by specifically blocking angiotensin II. Angiotensin II is a natural hormone produced in the body to keep blood pressure at normal levels. One function of angiotensin II is to increase blood pressure, usually when it becomes too low. Valsartan works by blocking the effect of angiotensin II. As a result, blood pressure is lowered.
- Hydrochlorothiazide is a diuretic or “water pill” that increases urination. This lowers blood pressure.

Together valsartan and hydrochlorothiazide lower blood pressure.

This medicine does not cure high blood pressure. It helps to control it. Therefore, it is important to continue taking DIOVAN-HCT regularly even if you feel fine.

If you have any questions about how DIOVAN-HCT works or why this medicine has been prescribed for you, ask your doctor.

When it should not be used:

Do not take DIOVAN-HCT if you:

- Are allergic to valsartan, hydrochlorothiazide or to any non-medicinal ingredient in the formulation.
 - Are allergic to any sulfonamide-derived drugs (sulfa drugs); most of them have a medicinal ingredient that ends in “-MIDE”. Ask your physician or pharmacist if you are not sure what sulfonamide-derived drugs are.
 - 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 difficulty urinating or produce no urine.
 - Suffer from severe liver disease with destruction of the small bile ducts within the liver (biliary cirrhosis) leading to the builds up bile in the liver (cholestasis).
 - 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-HCT during pregnancy can cause injury and even death to your baby.
 - Are breastfeeding. DIOVAN-HCT 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 DIOVAN-HCT.
- Have serious kidney disease.
 - Have a too low level of potassium or sodium or if you have a too high level of calcium in your blood despite treatment.
 - Have uric acid crystals in the joints (gout).

- Are under 18 years old.

If either of these apply to you, **tell your doctor without taking DIOVAN-HCT.**

What the medicinal ingredients are:

Valsartan and hydrochlorothiazide.

What the non-medicinal ingredients are:

DIOVAN-HCT tablets: Colloidal silicon dioxide, crospovidone, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, talc, and titanium dioxide.

In addition, the tablets also contain:

- DIOVAN-HCT 80/12.5 mg: Red and yellow iron oxide
- DIOVAN-HCT 160/12.5 mg: Red iron oxide
- DIOVAN-HCT 160/25 mg: Red, yellow and black iron oxide
- DIOVAN-HCT 320/12.5 mg: Red and black iron oxide
- DIOVAN-HCT 320/25 mg: Yellow iron oxide

If you are on a special diet, or if you are allergic to any substance, ask your doctor or pharmacist whether any of these ingredients may cause a problem.

What dosage forms it comes in:

Film-coated tablets, 80/12.5 mg (light orange), 160/12.5 mg (dark red), 160/25 mg (brown), 320/12.5 mg (pink), and 320/25 mg (yellow).

WARNINGS AND PRECAUTIONS

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

BEFORE you use DIOVAN-HCT 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 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, or a potassium-sparing diuretic (a specific kind of “water pill”).
- Are on a low-salt diet.
- Are less than 18 years old.
- Suffer from severe liver disease with destruction of the small bile ducts within the liver (biliary cirrhosis) leading to the builds up bile in the liver (cholestasis);
- Ever had swelling mainly of the face and throat while taking other drugs (including an ACE-inhibitor). If you get those symptoms, **stop taking DIOVAN-HCT and contact your doctor straight away. You should never take DIOVAN-HCT again;**
- Have low levels of potassium in your blood (with or without symptoms such as muscle weakness, muscle spasms, abnormal heart rhythm).
- Have low levels of sodium in your blood (with or without symptoms such as tiredness, confusion, muscle twitching, convulsions).
- Have high levels of calcium in your blood (with or without symptoms such as nausea, vomiting, constipation, stomach pain, frequent urination, thirst, muscle weakness and twitching).
- Have high levels of uric acid in the blood.
- Are suffering from allergy or asthma
- have high levels of cholesterol or triglycerides in your blood;
- Are suffering from vomiting or diarrhea, or taking high doses of a diuretic (water pill);
- Are taking a medicine that contains aliskiren, such as RASILEZ, used to lower high blood pressure. The combination with DIOVAN-HCT is not recommended.
- Are taking an angiotensin converting enzyme (ACE) inhibitor.
- 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.

Risk of skin cancer:

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

Hydrochlorothiazide in DIOVAN-HCT 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 DIOVAN-HCT.

You may become sensitive to the sun while taking DIOVAN-HCT. Exposure to sunlight should be minimized until you know how you respond.

You should have regular blood tests before and during treatment with DIOVAN-HCT. These will monitor the amount of electrolytes (such as potassium, sodium, calcium or magnesium) in your blood and may also monitor your kidney function

You are pregnant, breast-feeding or thinking of becoming pregnant?

Taking DIOVAN-HCT 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 DIOVAN-HCT, contact immediately your doctor.

It is also advisable not to take DIOVAN-HCT during breast-feeding. The diuretic component of DIOVAN-HCT passes into the breast milk and may also reduce your milk supply. If you are breast-feeding, avoid using DIOVAN-HCT unless recommended by your doctor.

Similar medicines were associated with serious harm to fetuses when they were taken during pregnancy. It is therefore important to tell your doctor immediately if you think you may have become pregnant, or planning to become pregnant. Your doctor will discuss with you the potential risk of taking DIOVAN-HCT during pregnancy.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to DIOVAN-HCT. 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 medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

Certain medicines tend to increase your blood pressure, for example, non prescription preparations for appetite control, asthma, colds, coughs, hay fever and sinus problems.

Before surgery and general anesthesia (even at the dentist's office), tell the physician or dentist that you are taking DIOVAN-HCT, as there may be a sudden

drop in blood pressure associated with general anesthesia.

The following may interact with DIOVAN-HCT:

- 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.
- Bile acid resins used to lower cholesterol.
- Other blood pressure lowering drugs, including ACE inhibitors or aliskiren.
- Calcium or vitamin D supplements.
- Corticosteroids used to treat joint pain and swelling.
- Digoxin, a heart medication, or other digitalis glycosides.
- 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.
- Lithium, antipsychotics, medicines used to treat some psychological conditions such as bipolar disease.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurare.
- other diuretics (water pills),
- Pressor amines such as epinephrine (substances that raise blood pressure),
- Potassium-sparing agents
- Potassium supplement, salt substitutes containing potassium or other drugs that may increase potassium levels. Your doctor may monitor the levels of potassium in your blood periodically,
- Some antibiotics (rifamycin group), a drug used to protect against transplant rejection (cyclosporine) or an antiretroviral drug used to treat HIV/AIDS infection (ritonavir). These drugs may increase the effect of DIOVAN-HCT.
- Amantadine (medicine to treat Parkinson's disease and also used to treat or prevent certain illnesses caused by viruses),
- Anticholinergic agents (medicines used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson's disease and as an aid to anaesthesia)
- Cortisone-like medicines, carbenoxolone (a medicine used to treat ulceration and inflammation), antibiotics such as penicillin G, antiarrhythmics (medicines used to treat heart problems),
- Cyclosporine (a medicine used in transplantation and in autoimmune disorders)
- Warfarin (medicine to prevent blood clot)
- Diazoxide (medicine to increase blood glucose level)

Taking carbamazepine with hydrochlorothiazide (a medicinal ingredient in DIOVAN-HCT) may cause a low sodium level in the blood. Symptoms of low sodium level in the blood may include: nausea, vomiting, headache, muscular cramps or weakness, and general uneasiness. As it worsens, confusion, decreased consciousness, convulsions (fits), or coma may occur. Tell your doctor if this happens to you.

Sedatives, tranquilizers, narcotics, alcohol and analgesics may increase the blood-pressure lowering effect of DIOVAN-HCT, so tell your physician or pharmacist if you are taking any of these.

PROPER USE OF THIS MEDICATION

Take DIOVAN-HCT exactly as prescribed. It is recommended to take your dose at about the same time everyday.

DIOVAN-HCT can be taken with or without food. If DIOVAN-HCT causes upset stomach, take it with food or milk.

Patients who have high blood pressure often do not notice any signs or symptoms of this condition. So even though you are feeling well, your health may be getting worse. This makes it all the more important for you to continue your treatment program and to keep your appointments with your doctor.

If you have any questions about how long to take DIOVAN-HCT, talk to your doctor or your pharmacist.

Usual Adult dose:

Take DIOVAN-HCT as directed. Dosage must be individualized. DIOVAN-HCT is not for initial therapy. Once you are stabilized on both individual components of DIOVAN-HCT the usual dosage is one 80 mg/12.5mg tablet once a day. In some cases, your doctor may prescribe a higher dose (e.g., the 160mg/12.5mg, 160 mg/25 mg, 320mg/12.5mg or the 320mg/25mg tablet).

Overdose:

If you experience severe dizziness and/or fainting, contact your doctor immediately so that medical attention may be given promptly.

If you think you have taken too much DIOVAN-HCT contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison control Centre immediately, even if there are no symptoms.

Missed Dose:

Try to take your dose at the same time each day, preferably in the morning. If you have forgotten to take your dose during the day, carry on with the next one at the usual time. Do not double doses.

- bleeding under the skin, rash, red patches on the skin
- drowsiness, insomnia
- reduced libido
- joint pain
- Cough
- Fatigue (unusual tiredness or weakness, sometimes sign of potassium loss)
- Upper respiratory tract infection
- Blistering skin (sign of dermatitis bullous)

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

- DIOVAN-HCT 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 help
		Only if severe	In all cases	
Common	<i>Allergic reactions:</i> Skin rash, skin eruption or other effect on the skin or eyes			✓
	<i>Low Blood Pressure:</i> dizziness, fainting, lightheadedness. May occur when you go from lying or sitting to standing up.	✓		

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- back or leg pain, muscle cramps, spasms and pain, weakness, restlessness
- dizziness, pins and needles in your fingers, headache
- constipation, diarrhea, nausea, vomiting, decreased appetite, upset stomach, enlargement of the glands in your mouth

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 help
	Only if severe	In all cases	
		✓	
<i>Decreased or increased levels of potassium in the blood:</i> irregular heartbeats, muscle weakness and generally feeling unwell		✓	
<i>Non-melanoma skin cancer:</i> 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	<i>Kidney Disorder:</i> change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue	✓	
	<i>Liver Disorder:</i> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite	✓	

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 help
	Only if severe	In all cases	
	✓		
<i>Increased blood sugar:</i> frequent urination, thirst, and hunger	✓		
<i>Electrolyte Imbalance:</i> weakness, drowsiness, muscle pain or cramps, irregular heartbeat		✓	
Abdominal pain		✓	
Rare		✓	
<i>Rhabdo-myolysis:</i> muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine		✓	
<i>Decreased White Blood Cells:</i> infections, fatigue, fever, aches, pains, and flu-like symptoms		✓	
<i>Decreased Platelets:</i> bruising, bleeding, fatigue and weakness		✓	
Very rare			✓
<i>Toxic Epidermal Necrolysis:</i> severe skin peeling, especially in mouth and eyes			✓

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 help
	Only if severe	In all cases	
Unknown	<i>Eye disorders:</i> - Myopia: sudden near sightedness or blurred vision - Glaucoma: increased pressure in your eyes, eye pain		✓
	<i>Anemia:</i> fatigue, loss of energy, weakness, shortness of breath.	✓	
	<i>Inflammation of the Pancreas:</i> abdominal pain that lasts and gets worse when you lie down, nausea, vomiting	✓	
	Blistering skin reactions with symptoms such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling and fever		✓
	Possible signs of a blood disorder (symptoms like sore throat, fever, or chills)		✓
Rare or very rare	Jaundice: Yellow eyes or skin		✓
	Irregular heart beat	✓	

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 help
	Only if severe	In all cases	
Necrotizing vasculitis; (Inflammation of vessels with or without pain)	✓		
Tiredness, confusion, muscle twitching, convulsions (possible symptoms of hypernatremia)			✓
Respiratory problems including pneumonitis and pulmonary edema			✓
Bone marrow failure, aplastic anemia: (Weakness, bruising and frequent infections)	✓		

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

HOW TO STORE IT

Store your DIOVAN-HCT tablets in a dry place at room temperature (15-30°C).

Do not take DIOVAN-HCT past the expiry date shown on the pack.

Always remember

This medicine has been prescribed to you for your current medical problem only. Do not give it to other people.

It is very important that you take this medicine exactly as your doctor tells you in order to get the best results and reduce the chance of side effects.

Keep out of reach and sight of children.

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.novartis.ca>

or by contacting the sponsor at:
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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:

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- **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 side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

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