

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

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

Serious Warnings and Precautions

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

What is DIOVAN-HCT used for?

DIOVAN-HCT is used in adults to treat mild to moderate essential hypertension (high blood pressure).

How does DIOVAN-HCT work?

DIOVAN-HCT is a combination tablet of two medicinal ingredients, valsartan and hydrochlorothiazide. Valsartan is an angiotensin receptor blocker (ARB) that helps relax blood vessels. This makes it easier for your heart to pump blood around your body. While hydrochlorothiazide is a diuretic or “water pill” that increases urination. These work together to lower high blood pressure.

What are the ingredients in DIOVAN-HCT?

Medicinal ingredients: Valsartan and hydrochlorothiazide

Non-medicinal ingredients: Colloidal silicon dioxide, crospovidone, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, talc, and titanium dioxide.

In addition, the tablets also contain:

- 80 mg/12.5 mg tablets: red iron oxide and yellow iron oxide
- 160 mg/12.5 mg tablets: red iron oxide
- 160 mg/25 mg tablets: black iron oxide, red iron oxide and yellow iron oxide

- 320 mg/12.5 mg tablets: black iron oxide and red iron oxide
- 320 mg/25mg tablets: yellow iron oxide

DIOVAN-HCT comes in the following dosage forms:

Tablets:

- 80 mg valsartan/12.5 mg hydrochlorothiazide (light orange)
- 160 mg valsartan/12.5 mg hydrochlorothiazide (dark red)
- 160 mg valsartan/25 mg hydrochlorothiazide (brown)
- 320 mg valsartan/12.5 mg hydrochlorothiazide (pink)
- 320 mg valsartan/25 mg hydrochlorothiazide (yellow)

Do not use DIOVAN-HCT if:

- you are allergic to valsartan, hydrochlorothiazide or to any other ingredients in DIOVAN-HCT.
- Have one of the following rare hereditary diseases:
 - Galactose intolerance;
 - Lapp lactase deficiency; or
 - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in DIOVAN-HCT.

- you are allergic to any sulfonamide-derived medicines (also known as “sulfa drugs”). Most of them have a medicinal ingredient that ends in “-**MIDE**”. Ask your healthcare professional if you are not sure what sulfonamide-derived medicines are.
- you have anuria (difficulty urinating or producing no urine).
- you have severe kidney problems.
- during treatment with DIOVAN-HCT you have:
 - oliguria (low urine output); or
 - progressive azotemia (high levels of nitrogen in the blood).
- you have electrolyte disturbances such as:
 - hyponatremia (low level of sodium in the blood); or
 - hypercalcemia (high level of calcium in the blood).
- you have a medical condition that involves a low level of potassium in the blood.
- you have gout or kidney stones due to high levels of uric acid in the blood.
- 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-HCT. 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);
 - penicillin (used to treat bacterial infections).
- have or have had heart problems (e.g., heart failure, narrowing of an artery or a heart valve).
- have or have had problems that affect the blood flow and blood vessels in the brain (e.g., stroke).
- have diabetes.
- have liver problems. This includes if you suffer from a medical condition that involves a blockage of the bile ducts (tubes that carry bile from the liver and gallbladder to the small intestine).
- 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 lupus erythematosus (an autoimmune disease).
- have a history of allergies or bronchial asthma.
- are planning to have surgery or anesthesia.
- have been told by a healthcare professional that you have hyperuricemia (high levels of uric acid in the blood) and are at risk of gout (a type of arthritis that causes joint pain).
- have edema (swelling caused by excess fluid in body tissues) in hot weather.
- are at a higher risk of developing skin cancer. You may be at a higher risk if you have light skin colour, have a personal or family history of skin cancer, or if you are taking medicines that suppress your immune system.
- 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 DIOVAN-HCT, stop the medication and seek medical attention immediately.

Other warnings you should know about:

DIOVAN-HCT can cause the following:

- **Angioedema** (swelling of tissue under the skin): Treatment with valsartan, a component of DIOVAN-HCT, 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-HCT and tell your healthcare professional right away.
- **Skin cancer:** Hydrochlorothiazide in DIOVAN-HCT may increase the risk of developing skin cancer such as non-melanoma skin cancer (NMSC), squamous cell carcinoma (SCC), and basal cell carcinoma (BCC). 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:
 - you should regularly check your skin for new lesions (e.g., a lump, bump, sore, or patch). These are more likely to occur in areas that are more exposed to the sun (e.g., face, ears, hands, shoulders, upper chest, and back).
 - you should limit your exposure to the sun, avoid indoor tanning, and use sun protection when going outside. This includes using sunscreen (SPF 30 or higher), wearing protective clothing, and wearing a hat.
 - tell your healthcare professional right away if you get more sensitive to the sun or UV light, or if you develop an unexpected lesion.
- **Photosensitivity:** You may become sensitive to the sun while taking DIOVAN-HCT. Exposure to sunlight should be reduced until you know how you respond. Tell your healthcare professional if you notice any photosensitivity. They may decide to stop your treatment with DIOVAN-HCT.
- **Hypotension** (low blood pressure): Treatment with DIOVAN-HCT can cause hypotension, in some cases even after the first dose. 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.
- **Fluid or electrolyte imbalance:** Hydrochlorothiazide in DIOVAN-HCT can cause fluid or electrolyte imbalances such as:
 - hypokalemia (low level of potassium in the blood),
 - hyponatremia (low level of sodium in the blood),
 - hypochloremic alkalosis (low level of chloride in the blood),
 - hyperuricemia (high uric acid levels in the blood), and
 - acute gout (a type of arthritis that causes joint pain).

Tell your healthcare professional if you notice any signs or symptoms related to fluid or electrolyte imbalances.

- **Eye problems:** Hydrochlorothiazide in DIOVAN-HCT can cause sudden eye disorders:
 - **Choroidal effusion** (an abnormal build-up of liquid in your eye that may result in vision changes),

- **Myopia** (sudden nearsightedness or blurred vision), and
- **Glaucoma** (an increased pressure in your eye). If left untreated, it may lead to permanent vision loss.

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

- **Kidney problems:** Treatment with DIOVAN-HCT 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.

Use of anesthesia: Before surgery and general anesthesia (even at the dentist's office), tell the doctor or dentist that you are taking DIOVAN-HCT, as there may be a sudden drop in blood pressure associated with general anesthesia.

Driving and using machines: DIOVAN-HCT 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-HCT.

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 the health of your kidneys and liver, your blood pressure and the profile of your blood.
- Your healthcare professional may stop your treatment with DIOVAN-HCT before performing tests to assess the health of your parathyroid glands.

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-HCT 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-HCT:

- other medicines used to lower high blood pressure such as guanethidine, methyldopa, ACE inhibitors, ARBs, beta blockers, vasodilators, calcium channel blockers and direct renin inhibitors.

- 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, rifampin, and penicillin.
- medicines used to treat fungal infections such as amphotericin B.
- medicines used to treat bipolar disorder such as lithium.
- medicines used to suppress the immune system such as cyclosporine.
- medicines used to treat HIV/AIDS such as ritonavir.
- medicines used to help with sleep such as barbiturates.
- medicines used to help reduce intense pain such as narcotics.
- medicines used to treat Parkinson’s Disease such as amantadine.
- medicines used to treat diabetes (antidiabetics) such as insulin and oral hypoglycemic agents (used to lower glucose levels in the blood).
- medicines used to treat cancer such as cyclophosphamide and methotrexate.
- medicines used to lower cholesterol such as bile acid resins (e.g., cholestyramine).
- vitamins and mineral supplements such as calcium or vitamin D.
- medicines used to treat epilepsy such as carbamazepine and topiramate.
- medicines known as corticosteroids that are used to treat joint pain, swelling, and other conditions.
- medicines used to treat West Syndrome such as adrenocorticotrophic hormone (ACTH).
- medicines used to treat low blood sugar such as diazoxide.
- medicines used to treat heart conditions such as digoxin.
- medicines that change the speed of bowel movements such as atropine, metoclopramide, and domperidone.
- medicines used to treat gout (a type of arthritis that causes joint pain) such as allopurinol, probenecid, uricosurics, and xanthine oxidase inhibitors.
- medicines used to treat acid peptic disease such as carbenoxolone.
- medicines used to treat an abnormal heartbeat.
- medicines known as sympathomimetic agents that reduce nasal congestion such as cough and cold medicines, or are used to treat asthma.
- medicines used to prevent and treat malaria such as chloroquine.
- medicines that have the potential to increase your blood pressure such as norepinephrine.

- medicines used to treat depression (antidepressants) such as selective serotonin re-uptake inhibitors (e.g., citalopram, escitalopram, and sertraline).
- medicines used to relieve muscle spasms such as tubocurarine.
- medicines known as anesthetics that block pain during surgery or certain medical procedures.
- medicines that slow down brain activity such as sedatives.
- alcohol.

How to take DIOVAN-HCT:

- DIOVAN-HCT is not for initial therapy.
- You must be stabilized on valsartan and hydrochlorothiazide before taking DIOVAN-HCT. If your dosage matches the dosages in DIOVAN-HCT, your healthcare professional may prescribe DIOVAN-HCT (instead of each medicinal ingredient as a separate pill).
- Your healthcare professional will decide the dose and length of DIOVAN-HCT for you. They may start with a low dose and slowly adjust the dose as needed. Take DIOVAN-HCT exactly as prescribed by your healthcare professional.
- DIOVAN-HCT can be taken with or without food, but it should be taken the same way each day. If DIOVAN-HCT causes upset stomach, take it with food or milk.
- It is recommended that you take your daily dose at about the same time every day, preferably in the morning.
- Your healthcare professional will monitor your health throughout your treatment and may interrupt, reduce or stop your dose.

Usual dose:

- Your healthcare professional will decide the best dose for you.
- The maximum daily dose is 320 mg valsartan and 25 mg hydrochlorothiazide.

Overdose:

Signs of an overdose with DIOVAN-HCT may include:

- low blood pressure that can lead to shock (rapid breathing, pale skin, cold and sweaty skin), decreased consciousness or a rapid heartbeat.
- low electrolyte levels in the blood, which may cause you to feel weak, dizzy, confused, tired, have cramps, vomit.
- dehydration.

If you think you, or a person you are caring for, have taken too much DIOVAN-HCT, 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-HCT?

These are not all the possible side effects you may have when taking DIOVAN-HCT. 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, motion sickness, fainting
- diarrhea, constipation, nausea, vomiting, gas, indigestion, decreased appetite, stomach flu or discomfort, dry mouth, toothache
- upper respiratory tract infection, runny or stuffy nose, cough, throat pain, bronchitis (inflammation of the lining of your lungs)
- fatigue, lack of energy
- pain or swelling of the hands, arms, legs or feet
- burning or prickling sensation of the skin, numbness, itchy skin
- bladder infection, frequent urination during the day
- sexual difficulties, impotence, decreased sexual desire
- problems with sleeping, anxiety
- headache
- fever
- feeling dehydrated
- back or neck pain
- sprains and strains, muscle spasm
- ringing in the ears, ear pain
- pink eye
- excessive sweating
- 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 reaction / Angioedema: rash, hives, swelling of the face, lips, tongue or throat,			✓

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	
difficulty swallowing or breathing, effect on the eyes, itching, fever, wheezing, drop in blood pressure, or feeling sick to your stomach and throwing up			
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	✓		
Decreased or increased levels of potassium in the blood: irregular heartbeats, muscle weakness, generally feeling unwell, muscle spasms, cramping, constipation, feeling of skipped heart beats or palpitations, fatigue, tingling, or numbness		✓	
Non-melanoma skin cancer: lump or discoloured patch on the skin that stays after a few weeks and slowly changes; lumps can be red/pink, firm and sometimes turn into ulcers; and cancerous patches are usually flat and scaly		✓	
UNCOMMON			
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		✓	
Hyperglycemia (high blood sugar): frequent urination, thirst, and hunger, dry skin, headache, blurred vision, or fatigue	✓		
Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		✓	

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	
Myocardial infarction (heart attack): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint, palpitations, or possible irregular heartbeat			✓
Abdominal pain		✓	
RARE			
Rhabdomyolysis (breakdown of damaged muscle): muscle tenderness, weakness, red-brown (tea-coloured) urine		✓	
Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms		✓	
Decreased Platelets: bruising, bleeding, fatigue and weakness		✓	
Arrhythmia (abnormal heart rhythms): rapid, slow or irregular heartbeat		✓	
Increased levels of uric acid in the blood: swelling, redness in the joints, sudden and intense attacks of joint pain (gout attack)		✓	
Photosensitivity (sensitivity to sunlight): itchy, red skin when exposed to sunlight			✓
Depression (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive) and thoughts of death or suicide. If you have a history of depression, your depression may become worse			✓
VERY RARE			
Necrotizing vasculitis: Inflammation of vessels with or without pain	✓		

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	
Acute respiratory distress (inflammation of lung tissue or excess fluid in the lungs): severe shortness of breath or difficulty breathing, fever, weakness, and confusion			✓
Bone marrow failure, aplastic anemia (body fails to produce enough new blood cells): weakness, bruising and frequent infections	✓		
Worsening or activation of lupus: fatigue, fever, joint pain, stiffness and swelling, rash on the face that covers the cheeks and the bridge of the nose or rashes elsewhere on the body, skin lesions, shortness of breath, chest pain, dry eyes, headaches, confusion and memory loss		✓	
UNKNOWN FREQUENCY			
Eye disorders: <ul style="list-style-type: none"> • Myopia: sudden near sightedness or blurred vision • Glaucoma: increased pressure in your eyes, eye pain, decrease in vision • Choroidal effusion: (build-up of liquid in your eye): blind spots, eye pain, or blurred vision 			✓
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.			✓
Anemia (decreased number of red blood cells): fatigue, loss of energy, weakness, shortness of breath, irregular heartbeats, or pale complexion		✓	
Pancreatitis (inflammation of the pancreas): upper abdominal pain that lasts and gets		✓	

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	
worse when you lie down, nausea, vomiting, fever, rapid heartbeat, or tenderness when touching the abdomen			

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-30°C). Protect from moisture.
- Do not take DIOVAN-HCT past the expiry date shown on the pack.
- Keep out of reach and sight of children.

If you want more information about DIOVAN-HCT:

- 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 Pharmaceutical Canada Inc.

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