

CONSUMER INFORMATION**PrDIOVAN*-HCT
valsartan and hydrochlorothiazide tablets**

This leaflet is part III of a three-part "Product Monograph" published when DIOVAN*-HCT was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DIOVAN*-HCT. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

DIOVAN*-HCT is a combination of an angiotensin II AT₁ receptor blocker (valsartan) and a diuretic (hydrochlorothiazide). Valsartan and hydrochlorothiazide work together to lower your 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:

The valsartan ingredient in DIOVAN*-HCT lowers blood pressure 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. The hydrochlorothiazide ingredient in DIOVAN*-HCT works by making your kidneys pass more water and salt. Together valsartan and hydrochlorothiazide lower blood pressure.

When it should not be used:

You should not take DIOVAN*-HCT if:

- you have ever had an unusual or allergic reaction to valsartan, hydrochlorothiazide or to any other component of this product;
- you are allergic to any sulfonamide-derived drugs (ask your physician or pharmacist if you are not sure what sulfonamide-derived drugs are);
- you are not passing urine;
- you are pregnant or planning to become pregnant (See WARNINGS AND PRECAUTIONS below).

DIOVAN*-HCT is not recommended for children.

What the medicinal ingredients are:

Valsartan and hydrochlorothiazide.

What the important nonmedicinal ingredients are:

DIOVAN*-HCT tablets also contain the following non-medicinal ingredients:

- 80/12.5 mg tablets: Colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose, hydroxypropyl methylcellulose, polyethylene glycol, red iron oxide, talc, titanium dioxide and yellow iron oxide.
- 160/12.5 mg: Colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose, hydroxypropyl methylcellulose, polyethylene glycol, red iron oxide, talc, and titanium dioxide.
- 160/25 mg: Colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose, hydroxypropyl methylcellulose, polyethylene glycol, black iron oxide, red iron oxide, talc, and titanium dioxide and yellow iron oxide.
- 320/12.5 mg: Colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose, hydroxypropyl methylcellulose, polyethylene glycol, red iron oxide, black iron oxide, talc, and titanium dioxide.
- 320/25 mg: Colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose, hydroxypropyl methylcellulose, polyethylene glycol, yellow iron oxide, talc, and titanium dioxide.

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:

DIOVAN*-HCT is available in five tablet strengths containing valsartan and hydrochlorothiazide 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg, 320 mg/12.5 mg, 320 mg/25 mg.

- The light orange, ovaloid, film coated tablet, imprinted with HGH on one side and CG on the other, contains 80 mg of valsartan and 12.5 mg of hydrochlorothiazide as the active ingredients.
- The dark red, ovaloid, film coated tablet, imprinted with HHH on one side and CG on the other, contains 160 mg of valsartan and 12.5 mg of hydrochlorothiazide.
- The brown, ovaloid, film coated tablet, imprinted with HXH on one side and NVR on the other, contains 160 mg of valsartan and 25 mg of hydrochlorothiazide.
- The pink, ovaloid, film coated tablet imprinted with "NVR" on one side and "HIL" on the other contains 320 mg of valsartan and 12.5 mg of hydrochlorothiazide.
- The yellow, ovaloid, film coated tablet imprinted with "NVR" on one side and "CTI" on the other contains 320 mg of valsartan and 25 mg of hydrochlorothiazide.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

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 physician as soon as possible.

BEFORE you use DIOVAN*-HCT talk to your doctor or pharmacist if:

- you have liver or kidney disease
- you have gout, diabetes, lupus erythematosus
- you are being treated with other diuretics (water pills)
- you are suffering from excess vomiting or diarrhea
- you have any allergies to this drug or its ingredients or components of the container
- you are breastfeeding

Do not take DIOVAN*-HCT if you are pregnant or planning to become pregnant.

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.

Although it is not known whether valsartan can pass into human breast milk, this does happen in animals. Hydrochlorothiazide appears in human milk. Therefore do not breast-feed during treatment. Tell your doctor if you are breast-feeding, so that other treatment options can be tried.

Like many other medicines used to treat high blood pressure, DIOVAN*-HCT may rarely cause dizziness and affect your concentration. So before you drive a vehicle, use machinery, or do other things that need concentration, make sure you know how you react to the effects of DIOVAN*-HCT.

INTERACTIONS WITH THIS MEDICATION

As with other medicines, interactions with other drugs are possible. Therefore, do not take any other medicines unless you have discussed the matter with your physician or your pharmacist.

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.

It is especially important for your physician and pharmacist to know if you are taking other drugs, such as:

- digoxin (a heart medicine)
- other diuretics (water pills),
- potassium-sparing agents
- potassium supplement or salt substitutes containing potassium
- resins (which reduce high cholesterol),
- medications to treat diabetes including insulin,
- cucare derivatives (muscle relaxants),
- allopurinol (anti-gout treatment)
- amantadine
- cytotoxic drugs (cancer therapy)
- anticholinergic agents
- cyclosporine
- pressor amines such as adrenaline,
- steroids,
- certain pain and arthritis medicines,
- lithium (a drug used to treat a certain kind of depression).

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

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.

Remember that this medicine does not cure your high blood pressure; it only may help to control it. Therefore, if you want to lower your blood pressure and keep it down, you must continue to take DIOVAN*-HCT as directed.

Usual 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).

You can take DIOVAN*-HCT with or without food, but it should be taken the same way each day.

Overdose:

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

For management of a suspected drug overdose, contact your regional Poison Control Centre.

Missed Dose:

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, DIOVAN*-HCT may cause unwanted reactions, or side effects. Most patients do not experience side effects from DIOVAN*-HCT, however, some patients may experience dizziness.

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 call your doctor or pharmacist
		Only if severe	In all cases	
Common	<i>Allergic reactions</i> Skin rash, skin eruption or other effect on the skin or eyes			✓
	Low Blood Pressure (hypotension): Fainting, dizziness, blurred vision			✓

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

Uncommon		Talk with your doctor or pharmacist		
	<i>Allergic reactions</i> Swelling of the lips, face or neck, accompanied by difficulty in breathing or speaking			✓
	<i>Kidney and Liver disorder</i> Symptoms such as nausea, vomiting dark/brown urine			✓
	Muscle tenderness or weakness, generalized weakness (sign of rhabdomyolysis)		✓	
	Abdominal pain		✓	

This is not a complete list of side effects. For any unexpected effects while taking DIOVAN-HCT, contact your doctor 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 this medicine out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345

By toll-free fax: 866-678-6789

Online: www.healthcanada.gc.ca/medeffect

By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:

Canada Vigilance National Office
Marketed Health Products Safety and
Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

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.

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 at:

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