

FDA-Approved Patient Labeling

PATIENT INFORMATION

DIOVAN HCT® (DYE'-o-van HCT)

(valsartan and hydrochlorothiazide)

Tablets

Read the Patient Information that comes with DIOVAN HCT before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition and treatment. If you have any questions about DIOVAN HCT, ask your doctor or pharmacist.

What is the most important information I should know about DIOVAN HCT?

DIOVAN HCT can cause harm or death to an unborn baby. Talk to your doctor about other ways to lower your blood pressure if you plan to become pregnant. If you get pregnant while taking DIOVAN HCT, tell your doctor right away.

What is DIOVAN HCT?

DIOVAN HCT contains 2 prescription medicines:

1. valsartan, an angiotensin receptor blocker (ARB)
2. hydrochlorothiazide (HCTZ), a water pill (diuretic)

DIOVAN HCT may be used to lower high blood pressure (hypertension) in adults-

- when 1 medicine to lower your high blood pressure is not enough.
- as the first medicine to lower high blood pressure if your doctor decides you are likely to need more than 1 medicine.

DIOVAN HCT has not been studied in children under 18 years of age.

Who should not take DIOVAN HCT?

Do not take DIOVAN HCT if you:

- **are allergic to any of the ingredients in DIOVAN HCT.** See the end of this leaflet for a complete list of ingredients in DIOVAN HCT.
- make less urine due to kidney problems.
- are allergic to medicines that contain sulfonamides.

What should I tell my doctor before taking DIOVAN HCT?

Tell your doctor about all your medical conditions, including if you:

- **are pregnant or plan to become pregnant.** See “What is the most important information I should know about DIOVAN HCT?”
- **are breastfeeding.** DIOVAN HCT passes into breast milk. It is not known if DIOVAN HCT effects your breastfed baby or milk production. Do not breastfeed while you are taking DIOVAN HCT.
- **have liver problems**
- **have kidney problems**
- **have or had gallstones**
- **have Lupus**
- **have low levels of potassium** (with or without symptoms such as muscle weakness, muscle spasms, abnormal heart rhythm) or magnesium in your blood
- **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.**

- **have ever had a reaction called angioedema, to another blood pressure medication. Angioedema causes swelling of the face, lips, tongue, throat and may cause difficulty breathing**

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Some of your other medicines and DIOVAN HCT could affect each other, causing serious side effects. Especially, tell your doctor if you take:

- other medicines for high blood pressure or a heart problem
- water pills (diuretics)
- potassium supplements. Your doctor may check the amount of potassium in your blood periodically.
- a salt substitute. Your doctor may check the amount of potassium in your blood periodically.
- antidiabetic medicines including insulin
- narcotic pain medicines
- sleeping pills
- lithium, a medicine used in some types of depression (Eskalith[®], Lithobid[®], Lithium Carbonate, Lithium Citrate)
- aspirin or other medicines called non-steroidal anti-inflammatory drugs (NSAIDs), like ibuprofen or naproxen
- digoxin or other digitalis glycosides (a heart medicine)
- muscle relaxants (medicines used during operations)
- certain cancer medicines, like cyclophosphamide or methotrexate
- certain 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 valsartan.

Ask your doctor if you are not sure if you are taking one of these medicines.

Know the medicines you take. Keep a list of your medicines with you to show to your doctor and pharmacist when a new medicine is prescribed. Talk to your doctor or pharmacist before you start taking any new medicine. Your doctor or pharmacist will know what medicines are safe to take together.

How should I take DIOVAN HCT?

- Take DIOVAN HCT exactly as prescribed by your doctor. Your doctor may change your dose if needed.
- Take DIOVAN HCT once each day.
- DIOVAN HCT can be taken with or without food.
- If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take the missed dose. Just take the next dose at your regular time.
- If you take too much DIOVAN HCT, call your doctor or Poison Control Center, or go to the nearest hospital emergency room.

What should I avoid while taking DIOVAN HCT?

You should not take DIOVAN HCT during pregnancy. See **“What is the most important information I should know about DIOVAN HCT?”**

What are the possible side effects of DIOVAN HCT?

DIOVAN HCT may cause serious side effects including:

- **Harm to an unborn baby causing injury and even death.** See **“What is the most important information I should know about DIOVAN HCT?”**

- **Low blood pressure (hypotension).** Low blood pressure is most likely to happen if you:

- take water pills
- are on a low-salt diet
- get dialysis treatments
- have heart problems
- get sick with vomiting or diarrhea
- drink alcohol

Lie down if you feel faint or dizzy. Call your doctor right away.

- **Allergic reactions.** People with and without allergy problems or asthma who take DIOVAN HCT may get allergic reactions.
- **Worsening of Lupus.** Hydrochlorothiazide, one of the medicines in DIOVAN HCT may cause Lupus to become active or worse.
- **Fluid and electrolyte (salt) problems.** Tell your doctor about any of the following signs and symptoms of fluid and electrolyte problems:
 - dry mouth
 - thirst
 - lack of energy (lethargic)
 - weakness
 - drowsiness
 - restlessness
 - confusion
 - seizures
 - muscle pain or cramps
 - muscle fatigue
 - very low urine output
 - fast heartbeat
 - nausea and vomiting
- **Kidney problems.** Kidney problems may become worse in people that already have kidney disease. Some people will have changes on blood tests for kidney function and may need a lower dose of DIOVAN HCT. Call your doctor if you get swelling in your feet, ankles, or hands, or unexplained weight gain. If you have heart failure, your doctor should check your kidney function before prescribing DIOVAN HCT.
- **Skin rash.** Call your doctor right away if you have an unusual skin rash.
- **Eye problems.** One of the medicines in DIOVAN HCT can cause eye problems that may lead to vision loss. Symptoms of eye problems can happen within hours to weeks of starting DIOVAN HCT. Tell your doctor right away if you have:
 - decrease in vision
 - eye pain

Protect your skin from the sun and undergo regular skin cancer screening, as one of the medicines in DIOVAN HCT may cause non-melanoma skin cancer.

Other side effects were generally mild and brief. They generally have not caused patients to stop taking DIOVAN HCT.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of DIOVAN HCT. For a complete list, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How do I store DIOVAN HCT?

- Store DIOVAN HCT tablets at room temperature between 59°F to 86°F (15°C to 30°C).
- Keep DIOVAN HCT in a closed container in a dry place.

Keep DIOVAN HCT and all medicines out of the reach of children.

General information about DIOVAN HCT

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use DIOVAN HCT for a condition for which it was not prescribed. Do not give DIOVAN HCT to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about DIOVAN HCT. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about DIOVAN HCT that is written for health professionals. For more information about DIOVAN HCT, go to www.DIOVAN.com or call 1-888-669-6682.

What are the ingredients in DIOVAN HCT?

Active ingredients: Valsartan and hydrochlorothiazide

Inactive ingredients: colloidal silicon dioxide, crospovidone, hydroxypropyl methylcellulose, iron oxides, magnesium stearate, microcrystalline cellulose, polyethylene glycol, talc, and titanium dioxide.

What is high blood pressure (hypertension)?

Blood pressure is the force in your blood vessels when your heart beats and when your heart rests. You have high blood pressure when the force is too much. DIOVAN HCT can help your blood vessels relax and reduce the amount of water in your body so your blood pressure is lower. Medicines that lower blood pressure lower your risk of having a stroke or heart attack.

High blood pressure makes the heart work harder to pump blood throughout the body and causes damage to the blood vessels. If high blood pressure is not treated, it can lead to stroke, heart attack, heart failure, kidney failure, and vision problems.

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East Hanover, New Jersey 07936

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T2024-85

Revised: December 2024