

PATIENT INFORMATION

DIOVAN HCT® (DYE'-o-van HCT)

valsartan / hydrochlorothiazide tablets

80/12.5 mg, 160/12.5 mg, 160/25 mg Rx only

Rx only

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?

If you get pregnant, stop taking DIOVAN HCT and call your doctor right away. DIOVAN HCT can harm an unborn baby causing injury and even death. If you plan to become pregnant, talk to your doctor about other treatment options before taking DIOVAN HCT.

What is DIOVAN HCT?

DIOVAN HCT contains two prescription medicines in one tablet: It contains:

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

DIOVAN HCT is used to lower high blood pressure (hypertension) in adults.

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.

Who should not take DIOVAN HCT?

Do not take DIOVAN HCT if you:

- **are allergic to any of the ingredients in DIOVAN HCT.** The active ingredients are valsartan and hydrochlorothiazide. See the end of this leaflet for a complete list of ingredients in DIOVAN HCT.
- have low urine output from kidney problems
- are allergic to medicines that contain sulfonamides. Ask your doctor or pharmacist about these medicines.

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

What should I tell my doctor before taking DIOVAN HCT?

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

- **are pregnant or planning to become pregnant.** See “What is the most important information I should know about DIOVAN HCT?”
- **are breastfeeding.** DIOVAN HCT passes into breast milk. You should choose either to take DIOVAN HCT or breastfeed, but not both.
- **have a heart condition**
- **have liver problems**
- **have kidney problems**
- **have or had gallstones**
- **have Lupus**

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Especially, tell your doctor if you are taking:

- other medicines for high blood pressure or a heart problem
- water pills (also called “diuretics”)
- potassium supplements or using a salt substitute containing potassium
- anti-diabetes medicine including insulin
- narcotic pain medicines
- sleeping pills
- lithium, a medicine used in some types of depression
- aspirin or other medicines called Non-steroidal Anti-Inflammatory Drugs (NSAIDS)

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 a day, at the same time 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 are the possible side effects of DIOVAN HCT?

DIOVAN HCT may cause the following serious side effects:

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

- **Kidney problems.** Kidney problems may get 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 get an unusual skin rash.

The most common side effects of DIOVAN HCT include:

- headache
- dizziness
- tiredness
- flu symptoms

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

Tell your doctor if you get any side effect that bothers you or that won't go away.

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

How do I store DIOVAN HCT?

- Store DIOVAN HCT tablets at room temperature between 59° to 86°F.
- 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, ask your pharmacist or doctor, visit www.DIOVAN.com on the Internet, or call 1-888-XXX-XXXX.

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

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