

16. HOW SUPPLIED/STORAGE AND HANDLING

Diovan HCT (valsartan and hydrochlorothiazide, USP) is available as non-scored tablets containing valsartan/hydrochlorothiazide 80/12.5 mg, 160/12.5 mg, 160/25 mg, 320/12.5 mg and 320/25 mg. All strengths are packaged in bottles of 90 tablets and unit dose blister packages.

80/12.5 mg Tablet - Light orange, ovaloid with slightly convex faces debossed CG on one side and HGH on the other side.

Bottles of 90	NDC 0078-0314-34
Unit Dose (blister pack)	NDC 0078-0314-06
Box of 100 (strips of 10)	

160/12.5 mg Tablet - Dark red, ovaloid with slightly convex faces debossed CG on one side and HHH on the other side.

Bottles of 90	NDC 0078-0315-34
Unit Dose (blister pack)	NDC 0078-0315-06
Box of 100 (strips of 10)	

160/25 mg Tablet - Brown orange, ovaloid with slightly convex faces debossed NVR on one side and HXH on the other side.

Bottles of 90	NDC 0078-0383-34
Unit Dose (blister pack)	NDC 0078-0383-06
Box of 100 (strips of 10)	

320/12.5 mg Tablet - Pink, ovaloid with beveled edge, debossed NVR on one side and HIL on the other side.

Bottles of 90	NDC 0078-0471-34
Unit Dose (blister pack)	NDC 0078-0471-06
Box of 100 (strips of 10)	

320/25 mg Tablet - Yellow, ovaloid with beveled edge, debossed NVR on one side and CTI on the other side.

Bottles of 90	NDC 0078-0472-34
Unit Dose (blister pack)	NDC 0078-0472-06
Box of 100 (strips of 10)	

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

Protect from moisture.

Dispense in tight container (USP).

17. PATIENT COUNSELING INFORMATION

17.1 Information for Patients

Pregnancy: Female patients of childbearing age should be told that use of drugs like Diovan HCT that act on the renin-angiotensin system during pregnancy can cause serious problems in the fetus and infant including: low blood pressure, poor development of skull bones, kidney failure and death. Discuss other treatment options with female patients planning to become pregnant. Women using Diovan HCT who become pregnant should notify their physician as soon as possible.

Symptomatic Hypotension: A patient receiving Diovan HCT should be cautioned that lightheadedness can occur, especially during the first days of therapy, and that it should be reported to the prescribing physician. The patients should be told that if syncope occurs, Diovan HCT should be discontinued until the physician has been consulted.

All patients should be cautioned that inadequate fluid intake, excessive perspiration, diarrhea, or vomiting can lead to an excessive fall in blood pressure, with the same consequences of lightheadedness and possible syncope.

Potassium Supplements: A patient receiving Diovan HCT should be told not to use potassium supplements or salt substitutes containing potassium without consulting the prescribing physician.

17.2 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?

If you become 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 to lower your high blood pressure before taking DIOVAN HCT.

What is DIOVAN HCT?

DIOVAN HCT contains two 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 one 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 one 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 breast-feeding.** DIOVAN HCT passes into breast milk. You should choose either to take DIOVAN HCT or breast-feed, but not both.
- **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. 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
- a salt substitute containing potassium
- 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).

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.

- **Worsening liver problems.** Liver problems may get worse in people who already have liver problems and take DIOVAN HCT.
- **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.

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 1-866-404-6359.

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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