



There were no clear differences in all-cause mortality based on age, gender, race, or baseline therapies, as shown in the figure above.

16. HOW SUPPLIED/STORAGE AND HANDLING

Diovan (valsartan) is available as tablets containing valsartan 40 mg, 80 mg, 160 mg, or 320 mg. All strengths are packaged in bottles and unit dose blister packages (10 strips of 10 tablets) as described below.

40 mg tablets are scored on one side and ovaloid with bevelled edges. 80 mg, 160 mg, and 320 mg tablets are unscored and almond-shaped with bevelled edges.

| Tablet | Color | Deboss | | NDC 0078-XXXX-XX | | |
|--------|------------------|--------|--------|------------------|-----------|---------|
| | | Side 1 | Side 2 | | Bottle of | Blister |
| | | | | 30 | 90 | |
| 40 mg | Yellow | NVR | DO | 0423-15 | – | 0423-06 |
| 80 mg | Pale red | NVR | DV | – | 0358-34 | 0358-06 |
| 160 mg | Grey-orange | NVR | DX | – | 0359-34 | 0359-06 |
| 320 mg | Dark grey-violet | NVR | DXL | – | 0360-34 | 0360-06 |

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 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. Women using Diovan who become pregnant should notify their physician as soon as possible.

DIOVAN (DYE'-o-van) (valsartan) Tablets

Read the Patient Information that comes with DIOVAN before you take 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 medical condition or treatment. If you have any questions about DIOVAN, ask your doctor or pharmacist.

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

Taking DIOVAN during pregnancy can cause injury and even death to your unborn baby. If you get pregnant, stop taking DIOVAN and call your doctor right away. Talk to your doctor about other ways to lower your blood pressure if you plan to become pregnant.

What is DIOVAN?

DIOVAN is a prescription medicine called an angiotensin receptor blocker (ARB). It is used in adults to:

- **lower high blood pressure (hypertension) in adults and children, 6 to 16 years of age.**
- treat heart failure in adults. In these patients, DIOVAN may lower the need for hospitalization that happens from heart failure.
- improve the chance of living longer after a heart attack (myocardial infarction) in adults.

DIOVAN is not for children under 6 years of age or children with certain kidney problems.

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 can help your blood vessels relax so your blood pressure is lower.

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.

Heart Failure occurs when the heart is weak and cannot pump enough blood to your lungs and the rest of your body. Just walking or moving can make you short of breath, so you may have to rest a lot.

Heart Attack (Myocardial Infarction): A heart attack is caused by a blocked artery that results in damage to the heart muscle.

What should I tell my doctor before taking DIOVAN?

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

- have any allergies. See the end of this leaflet for a complete list of ingredients in DIOVAN.
- have a heart condition
- have liver problems
- have kidney problems
- **are pregnant or planning to become pregnant.** See “What is the most important information I should know about DIOVAN?”
- are breast-feeding. It is not known if DIOVAN passes into your breast milk. You and your doctor should decide if you will take DIOVAN or breast-feed, but not both. Talk with your doctor about the best way to feed your baby if you take DIOVAN.

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

- other medicines for high blood pressure or a heart problem
- water pills (also called “diuretics”)
- potassium supplements
- a salt substitute

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?

- Take DIOVAN exactly as prescribed by your doctor.
- For treatment of high blood pressure, take DIOVAN one time each day, at the same time each day.
- **If your child cannot swallow tablets, or if tablets are not available in the prescribed strength, your pharmacist will mix DIOVAN as a liquid suspension for your child. If your child switches between taking the tablet and the suspension, your doctor will adjust the dose as needed. Shake the bottle of suspension well for at least 10 seconds before pouring the dose of medicine to give to your child.**
- For adult patients with heart failure or who have had a heart attack, take DIOVAN two times each day, at the same time each day. Your doctor may start you on a low dose of DIOVAN and may increase the dose during your treatment.
- DIOVAN 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. Take the next dose at your regular time.
- If you take too much DIOVAN, call your doctor or Poison Control Center, or go to the nearest hospital emergency room.

What are the possible side effects of DIOVAN?

DIOVAN may cause the following serious side effects:

Injury or death to an unborn baby. See “What is the most important information I should know about DIOVAN?”

Low Blood Pressure (Hypotension). Low blood pressure is most likely to happen if you also take water pills, are on a low-salt diet, get dialysis treatments, have heart problems, or get sick with vomiting or diarrhea. 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. 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.

The most common side effects of DIOVAN used to treat people with high blood pressure include:

- headache

- dizziness
- flu symptoms
- tiredness
- stomach (abdominal) pain

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

The most common side effects of DIOVAN used to treat people with heart failure include:

- dizziness
- low blood pressure
- diarrhea
- joint and back pain
- tiredness
- high blood potassium

Common side effects of DIOVAN used to treat people after a heart attack which caused them to stop taking the drug include:

- low blood pressure
- cough
- high blood creatinine (decreased kidney function)
- rash

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

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

How do I store DIOVAN?

- Store DIOVAN tablets at room temperature between 59° to 86°F (15°C - 30°C).
- Keep DIOVAN tablets in a closed container in a dry place.
- Store bottles of DIOVAN suspension at room temperature less than 86°F (30°C) for up to 30 days, or refrigerate between 35°F - 46°F (2°C - 8°C) for up to 75 days.
- **Keep DIOVAN and all medicines out of the reach of children.**

General information about DIOVAN

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use DIOVAN for a condition for which it was not prescribed. Do not give DIOVAN 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. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about DIOVAN that is written for health professionals.

For more information about DIOVAN, ask your pharmacist or doctor, visit www.DIOVAN.com on the Internet, or call **1-866-404-6361**.

What are the ingredients in DIOVAN?

Active ingredient: valsartan

Inactive ingredients: colloidal silicon dioxide, crospovidone, hydroxypropyl methylcellulose, iron oxides (yellow, black and/or red), magnesium stearate, microcrystalline cellulose, polyethylene glycol 8000, and titanium dioxide

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