**PATIENT INFORMATION**

DIOVAN® (DYE-o-van)

(valsartan) tablets

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

**DIOVAN can cause harm or death to an unborn baby.**

- Talk to your healthcare provider about other ways to lower your blood pressure if you plan to become pregnant.
- If you become pregnant during treatment with DIOVAN, stop taking DIOVAN and tell your healthcare provider right away.

**What is DIOVAN?**

DIOVAN is a prescription medicine used in:

- adults and children 1 year of age and older to lower high blood pressure (hypertension). DIOVAN may be used alone or in combination with other blood pressure medicines.
- adults to treat heart failure. DIOVAN may help decrease your need for hospitalization that happens with heart failure.
- adults with certain types of heart failure, to increase the chance of living longer after a heart attack (myocardial infarction).

DIOVAN should not be used to treat high blood pressure in children less than 1 year of age.

It is not known if DIOVAN is safe and effective in children with certain kidney problems.

**Do not take DIOVAN if you:**

- are allergic to any of the ingredients in DIOVAN. See the end of this leaflet for a complete list of ingredients in DIOVAN.
- have diabetes and are also taking aliskiren. Talk to your healthcare provider if you are not sure.

**Before taking DIOVAN, tell your healthcare provider about all of your medical conditions including, if you:**

- have heart problems
- have kidney problems
- **are pregnant or plan to become pregnant.** See **"What is the most important information I should know about DIOVAN?**
- are breastfeeding or plan to breastfeed. It is not known if DIOVAN passes into your breast milk. You should not breastfeed during treatment with DIOVAN. Talk with your healthcare provider about the best way to feed your baby during your treatment with DIOVAN.

**Tell your healthcare provider about all the medicines you take** including prescription and over- the-counter medicines, vitamins and herbal supplements. DIOVAN may affect the way other medicines work.

**Especially tell your healthcare provider if you take:**

- other medicines for high blood pressure or a heart problem
- water pills (also called "diuretics")
- potassium-containing medicines, potassium supplements or salt substitutes containing potassium. Your healthcare provider may check the amount of potassium in your blood regularly.
- nonsteroidal anti-inflammatory drugs (NSAIDs)
- Lithium. Your healthcare provider will check the amount of lithium in your blood regularly.

Know the medicines you take. Keep a list of your medicines with you to show to your healthcare provider and pharmacist when a new medicine is prescribed. Talk to your healthcare provider or pharmacist before you start taking any new medicine.

**How should I take DIOVAN?**

- Take DIOVAN exactly as prescribed by your healthcare provider.
- For treatment of high blood pressure, take DIOVAN 1 time each day
- **For children:** Your pharmacist will mix DIOVAN as a liquid suspension for your child, if:
  - your child is 1 to 5 years of age, or
  - your child is older than 5 years of age and cannot swallow tablets, or
  - if tablets are not available in the prescribed strength needed for your child
- If your child switches between taking the tablet and the suspension, your healthcare provider 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 adults** with heart failure or who have had a heart attack, take DIOVAN 2 times each day. Your healthcare provider 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 healthcare provider, or go to the nearest hospital emergency room.

**What are the possible side effects of DIOVAN?**

- **DIOVAN can cause serious side effects, including: See "What is the most important information I should know about DIOVAN?"**
- **Low blood pressure (hypotension).** Low blood pressure can happen with DIOVAN, especially when you first start taking it and can cause you to feel lightheaded. Feeling lightheaded is most likely to happen if you:
  - take water pills
  - are on a low-salt diet
  - get dialysis treatments
  - do not drink enough liquids
  - are dehydrated (decreased body fluids) due to vomiting and diarrhea
  - you sweat excessively
  - have heart problems

  Lie down, if you feel lightheaded, dizzy or faint. Call your healthcare provider right away.
- **Kidney problems.** Kidney problems may get worse in people that already have kidney disease or heart problems. Your doctor may do blood tests to check for this.
- **Increased potassium in your blood.** Some people may develop increased potassium in the blood during treatment with DIOVAN. Your doctor may do a blood test to check your potassium levels as needed.

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

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

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

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

**The most common side effects of DIOVAN when used to treat people after a heart attack that cause them to stop taking DIOVAN include:**

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

You should not stop taking DIOVAN without talking to your healthcare provider. These are not all of the possible side effects of DIOVAN. For more information, ask your healthcare provider or pharmacist.

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

**How should I store DIOVAN?**

- Store DIOVAN tablets at room temperature between 68ºF to 77ºF (20ºC to 25 ºC).
- Keep DIOVAN tablets container tightly closed and in a dry place to protect from moisture.
- DIOVAN suspension is provided in a glass bottle with a child-resistant screw-cap closure.
- Store bottles of DIOVAN suspension at room temperature less than 86ºF (30ºC) for up to 30 days, **or** refrigerate between 35ºF to 46ºF (2ºC to 8ºC) for up to 75 days.

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

**General information about the safe and effective use of DIOVAN.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. 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.

You can ask your healthcare provider or pharmacist for information about DIOVAN that is written for health professionals.

**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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For more information, go to www.DIOVAN.com or call 1-888-669-6682.

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