

DIOVAN® FILM-COATED TABLET

Valsartan (40mg, 80mg, and 160mg)

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What Diovan is used for

Diovan is used to treat high blood pressure in adults. High blood pressure increases the workload of the heart and arteries. If it continues for a long time, it can damage the blood vessels of the brain, heart, and kidneys, and may result in a stroke, heart failure, or kidney failure. High blood pressure increases the risk of heart attacks. Lowering your blood pressure to normal reduces the risk of developing these disorders.

Diovan is used to treat adult heart failure patients. Heart failure is associated with shortness of breath, and swelling of the feet and legs due to fluid build-up. Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body.

Diovan can also be used to treat adults after a heart attack (myocardial infarction) to improve survival and reduce further heart problems.

How Diovan works

Angiotensin II is a natural substance in the body that causes blood vessels to tighten, thus causing your blood pressure to increase. Diovan works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

If you have any question about how Diovan works or why this medicine has been prescribed for you, ask your doctor.

Before you use Diovan

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

-When you must not use it

- If you have ever had an unusual or allergic reaction to valsartan or to any other ingredients of this product listed at the end of this leaflet.
- If you are pregnant or planning to become pregnant.
- If you have high level of sugar in the blood and you are suffering from type 2 diabetes (also called non-insulin dependent diabetes mellitus) while you are taking a blood pressure lowering medicine called aliskiren

If either of these apply to you, **tell your doctor without taking Diovan.** If you think you may be allergic, ask your doctor for advice.

-Pregnancy and breast-feeding

Do not take Diovan if you are pregnant or planning to become pregnant. Use of similar medicines has been associated with serious harm to the unborn child. It is therefore important to check with your doctor immediately if you think you may have become pregnant or are planning to become pregnant. Your doctor will discuss with you the potential risk of taking Diovan during pregnancy.

Do not take Diovan while breast-feeding. Tell your doctor if you are breast-feeding.

-Before you start to use it

Warnings and precautions:

- **If you have** a liver disease
- If you have a serious kidney disease or are undergoing dialysis
- **If you are** already taking a medicine called ACE-inhibitor together with a beta blocker to treat your heart failure
- **If you are** suffering from vomiting or diarrhea or are taking high doses of a diuretic (water pill).
- **If you are** suffering from heart failure or have experienced a heart attack. Follow your doctor's instruction for the starting dose carefully. Your doctor may also check your kidney function.
- If you ever had a swelling mainly of the face and throat while taking

other drugs (including an ACE-inhibitor). If you get those symptoms, **stop taking Diovan and contact your doctor immediately. You should never take Diovan again.**

- If you are treated with an ACE-inhibitor or aliskiren

If any of these apply to you, tell your doctor before you take Diovan.

Older people (age 65 and over)

You can also use Diovan if you are 65 years of age or older.

Children

The safety and efficacy of Diovan have not been established in children

-Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This applies to both prescription and non-prescription medicines, especially:

- Medicines used to lower blood pressure, especially diuretics (water pills), ACE-inhibitors or aliskiren;
- Potassium-sparing medicines, potassium supplements, salt substitutes containing potassium or other drugs that may increase potassium levels. Your doctor may check the amount of potassium in your blood periodically;
- Certain type of pain killers called non-steroidal anti-inflammatory medicines (NSAIDs) or Selective Cyclooxygenase-2 Inhibitors (Cox-2 Inhibitors). Your doctor may also check your kidney function;
- Lithium, a medicine used to treat some types of psychiatric illness;
- Some antibiotics (rifamycin group), a drug used to protect against transplant rejection (cyclosporin) or an antiretroviral drug used to treat HIV/AIDS infection (ritonavir). These drugs

may increase the effect of Diovan.

How to use Diovan

Follow your doctor's instructions carefully. Do not exceed the recommended dose.

Patients who have high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it all the more important for you to keep your appointments with the doctor even if you are feeling well. It is very important that you take this medicine exactly as your doctor tells you in order to get the best results and reduce the risk of side effects.

Diovan is for oral use only.

Swallow Diovan tablets with a glass of water. Diovan tablets may be taken with or without food.

-How much to use

Your doctor will tell you exactly how many tablets of Diovan to take.

- To treat high blood pressure, the usual dosage is one 80 mg or 160 mg tablet once a day. In some cases, your doctor may prescribe a higher dose (e.g. 320 mg tablet) or an additional medicine (e.g. a diuretic).
- In heart failure, the treatment starts generally with 40 mg twice daily. The dose is gradually increased to 80 mg twice daily and 160 mg twice daily as tolerated by the patient.
- Following a heart attack, treatment is generally started as early as 12 hours, usually at a low dose of 20 mg twice daily. Your doctor will increase this dose gradually over several weeks to a maximum of 160 mg twice daily. You obtain the 20 mg dose by dividing the 40 mg tablet.

-When to use Diovan

Taking Diovan at the same time each day will help you remember when to take your medicine.

-How long to use Diovan

Continue to take Diovan as your doctor tells you.

If you have questions about how long to take Diovan, talk to your doctor or your pharmacist.

-If you forget to use Diovan

It is advisable to take your medicine at the same time each day, preferably in the morning. However, if you forget to take a dose of Diovan, carry on with the next one at the usual time. Do not take a double dose to make up for the forgotten dose.

-If you use too much (overdose)

If you have accidentally taken too many tablets of Diovan or more Diovan solution than you should, talk to your doctor.

If you experience severe dizziness and/or fainting, tell your doctor as quickly as possible.

While you are using Diovan

-Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Side effects

As with all medicines, patients taking Diovan can experience side effects, although not everybody gets them.

Some side effects could be serious

(frequency unknown: frequency cannot be estimated from the available data)

You may experience symptoms of angioedema (an allergic reaction), such as

- swollen face, tongue or throat
- difficulty in swallowing
- hives and difficulties in breathing

If you get any of these, tell your doctor immediately.

Some side effects are common

(these side effects may affect between 1 and 10 in every 100 patients):

- dizziness
- low blood pressure with symptoms such as dizziness
- decreased kidney function (signs of renal impairment)

Some side effects are uncommon

(these side effects may affect between 1 and 10 in every 1,000 patients):

- allergic reaction with symptoms such as rash, itching, dizziness, swelling of face or lips or tongue or throat, difficulty breathing or swallowing (signs of angioedema) - (see also "Some side effects could be serious" listed before)
- sudden loss of consciousness

- spinning sensation
- severely decreased kidney function (signs of acute renal failure)
- muscle spasms, abnormal heart rhythm (signs of hyperkalemia)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- headache
- cough
- abdominal pain
- nausea
- diarrhea
- tiredness
- weakness

If any of these affects you severely, tell your doctor.

If you notice any other side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumer → Reporting Side Effects to Medicines [ConSERF])

Storage and disposal of Diovan

Storage

- Do not use after the expiry date shown on the box.
- Do not store above 30°C.
- Store in the original package.
- Keep out of the reach and sight of children.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

Diovan 40 mg film-coated tablets are yellow, ovaloid, scored on one side, slightly convex, with beveled edges, debossed on one side with DO and with NVR on the other side.

Diovan 80 mg film-coated tablets are pale red, round, scored on one side, slightly convex, with beveled edges, debossed on one side with D/V and NVR on the other side.

Diovan 160 mg film-coated tablets are grey-orange, ovaloid, scored on

one side, convex, debossed on one side with DX/DX and NVR on the other side.

-Ingredients

- *Active ingredients*
valsartan.

- *Inactive ingredients*
microcrystalline cellulose,
crospovidone, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide (E171) Macrogol 8000, red iron oxide (E172), yellow iron oxide (E172), black iron oxide (E172) (40 mg, and 160 mg)

MAL Number

MAL09042429ARZ (40mg)
MAL09042430ARZ (80mg)
MAL09042431ARZ (160mg)

Manufacturer

40mg, 80mg and 160mg:
Novartis Farma S.p.A,
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Product Registration Holder

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