

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Diovan® 40 mg Film-coated Tablets

Composition:

Each film-coated tablet contains: Valsartan 40 mg

Diovan® 80 mg Film-coated Tablets

Composition:

Each film-coated tablet contains: Valsartan 80 mg

Diovan® 160 mg Film-coated Tablets

Composition:

Each film-coated tablet contains: Valsartan 160 mg

Inactive and allergenic ingredients: See section 2 "Before using the medicine" and section 6 "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Diovan 40 mg is intended for the treatment of heart failure and to reduce hospitalizations in patients with intolerance to angiotensin converting enzyme inhibitors (ACEi). For treatment following myocardial infarction, to improve survival.

Diovan 80 mg and Diovan 160 mg are intended for the treatment of hypertension. For the treatment of heart failure and to reduce hospitalizations in patients with intolerance to angiotensin converting enzyme inhibitors (ACEi). For treatment following myocardial infarction, to improve survival.

- Hypertension increases the workload of the heart and arteries. If the hypertension is not treated, damage to the blood vessels of the brain, heart and kidneys could result. The result may cause a stroke, heart failure or kidney failure. Hypertension increases the risk of heart attacks. Lowering blood pressure to normal levels reduces the risk of developing these disorders.
- For the treatment of adult patients following a heart attack (myocardial infarction), in order to improve survival and reduce additional heart problems.
- For the treatment of symptomatic heart failure in adult patients. Heart failure includes shortness of breath and swelling of the legs and feet due to fluid buildup. Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed by the body.

Therapeutic group:

Angiotensin II receptor antagonist.

Diovan belongs to a class of medicines that block the angiotensin II receptor, helping to control hypertension. Angiotensin II is a natural substance in the body that causes blood vessels to tighten, thus causing blood pressure to increase. Diovan works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient valsartan or to any of the additional ingredients contained in the medicine (detailed in section 6)
- You suffer from severe liver dysfunction
- You are more than 3 months pregnant (it is also preferable to avoid Diovan in early pregnancy – see "Pregnancy and breast-feeding" section)
- You are being treated with a blood pressure-lowering medicine containing aliskiren because you are a diabetic or suffer from impaired kidney function

If any of the above conditions apply to you, inform the doctor without taking Diovan.

Special warnings regarding use of the medicine: Before treatment with Diovan, tell the doctor if:

- You have a liver disease
- You have a severe kidney disease or you are undergoing dialysis
- You are suffering from narrowing of the kidney artery
- You have recently undergone a kidney transplantation
- You have a severe heart disease, other than heart failure or heart attack

- You have ever had swelling of the tongue and face caused by an allergic reaction called angioedema, when you took another medicine (including ACE inhibitors), tell your doctor. If these symptoms occur when you are taking Diovan, **stop taking Diovan immediately and never take Diovan again.** See also section 4, "Side Effects"
- If you experience abdominal pain, nausea, vomiting or diarrhea after taking Diovan, your doctor will decide on further treatment. Do not stop taking Diovan on your own
- You are taking medicines that increase the amount of potassium in the blood. This includes potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin. You may be required to check the amount of potassium in your blood at regular intervals
- You suffer from aldosteronism, a disease in which your adrenal glands produce excessive aldosterone hormone. In such a case, the use of Diovan is not recommended
- You have lost a large amount of fluid (dehydration) due to diarrhea or vomiting or high doses of diuretics
- You are taking any of the following medicines used to treat high blood pressure:
 - An ACE (angiotensin converting enzyme) inhibitor (e.g., enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems
 - Aliskiren
 - You are being treated with an ACE inhibitor together with other medicines to treat your heart failure, known as mineralocorticoid receptor antagonists (MRAs) (e.g., spironolactone, eplerenone) or beta blockers (e.g., metoprolol)

See also the information in the "Do not use the medicine if:" section.

You must tell the doctor if you think you are (or might be) pregnant. It is not recommended to take Diovan in early stages of pregnancy, **do not take Diovan** if you are more than 3 months pregnant, as serious harm could be caused to the unborn child if the medicine is used at that stage (see "Pregnancy and breast-feeding" section).

Children:

This medicine is not intended for infants, children and adolescents under 18 years of age.

Tests and follow-up:

Your doctor may test your kidney function, blood pressure and the amount of electrolytes (such as potassium) in your blood at regular intervals.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. The treatment can be affected if Diovan is taken together with certain medicines. It may be necessary to change the dosage, to take precautions, or, in some cases, to stop taking one of the medicines. In particular, inform the doctor or pharmacist if you are taking the following medicines:

- **Other medicines used for lowering blood pressure**, mainly diuretics, ACE inhibitors (such as: enalapril, lisinopril, etc.) or aliskiren (see also sections "Do not use the medicine if" and "Special warnings regarding use of the medicine")
- **Medicines that increase the amount of potassium** in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin
- **Certain type of pain killers** called non-steroidal anti-inflammatory drugs (NSAIDs)
- **Some antibiotics** (from the rifamycin group), a medicine used to protect against transplant rejection (cyclosporin) or an antiretroviral drug used to treat HIV/AIDS infection (ritonavir). These medicines may increase the effect of Diovan
- **Lithium**, a medicine used to treat certain types of psychiatric illnesses

In addition:

- If you are being **treated after a heart attack**, the combination with ACE inhibitors (a medicine to treat heart attack) is not recommended
- If you are being treated for **heart failure**, a triple combination with **ACE inhibitors, other medicines known as mineralocorticoid receptor antagonists (MRAs) (with blocking activity) to treat heart failure** (e.g., spironolactone, eplerenone) or **beta blockers** (e.g., metoprolol) **is not recommended**

Use of the medicine and food:

Diovan can be taken with or without food.

Pregnancy and breast-feeding:

- **Tell the doctor if you think you are pregnant (or might be pregnant).**

It can be assumed that your doctor will advise you to stop taking Diovan before you become pregnant or as soon as you know you are pregnant; and he will advise you to take another medicine instead of Diovan. Diovan is not recommended in the early stages of pregnancy, and **must not** be taken beyond the third month of pregnancy, as the medicine may cause serious harm to the baby if you used it after the third month of pregnancy.

- **Tell your doctor if you are breast-feeding or planning to start breast-feeding.** Diovan is not recommended for mothers who are breast-feeding, and your doctor will presumably choose

another treatment for you if you wish to breast-feed, especially if your baby was just born, or born prematurely.

Driving and operating machinery:

Before driving a vehicle, operating machinery or performing any activity that requires concentration, make sure you know how Diovan affects you. As with many other medicines used to treat high blood pressure, Diovan may cause dizziness and impairment of concentration.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only. The recommended dosage depends on the indication for which it was prescribed.

Diovan can be used in patients aged 65 and above.

This medicine is not intended for infants, children and adolescents under the age of 18.

Do not exceed the recommended dose.

Patients with high blood pressure usually do not notice signs of the problem. Many feel normal. It is therefore very important for you to keep your appointments with your doctor even if you are feeling well.

Method of administration:

Diovan may be taken with or without food. There is no information regarding crushing or chewing the film-coated tablet. Swallow Diovan with a glass of water. Take Diovan at the same time each day. For instructions regarding halving, please see the section "What the medicine looks like and the contents of the package".

If you accidentally take a high dosage

If you experience severe dizziness and/or fainting, refer to your doctor immediately and lie down. If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forget to take Diovan

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, skip the forgotten dose. Do not take a double dose. Take the next dose at the scheduled time and consult the doctor.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. Stopping the treatment may worsen your ailment. Before stopping, discuss the implications of stopping with the doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Diovan may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Some side effects can be serious and need immediate medical intervention: Refer to the doctor immediately if you have symptoms of angioedema (a specific allergic reaction) such as:

- swelling of the face, tongue or throat
- breathing and swallowing difficulties
- itching and hives

If you experience any of the symptoms mentioned, stop taking Diovan and contact your doctor immediately (see also section "Special warnings regarding use of the medicine").

Additional side effects:

Common side effects (effects that occur in up to 1 user in 10):

- Dizziness
- Low blood pressure, with or without symptoms, such as dizziness and fainting upon standing up
- Decreased kidney function (signs of kidney disorder)

Uncommon side effects (effects that occur in up to 1 user in 100):

- Allergic reaction (angioedema); see section "Special warnings regarding use of the medicine". Refer to the doctor immediately for medical assistance
- Sudden loss of consciousness (syncope)
- Spinning sensation (vertigo)
- Severely decreased kidney function (signs of acute renal failure)
- Muscle spasms, abnormal heart rhythm (signs of hyperkalemia - excess potassium)
- Breathlessness, breathing difficulties when lying down, swelling of the feet or legs (signs of heart failure)
- Headache
- Cough
- Abdominal pain
- Nausea
- Diarrhea
- Tiredness
- Weakness

Very rare (may affect up to 1 in 10,000 people):

- Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhea

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

- Blisters on the skin (sign of a bullous skin inflammation [dermatitis])

- Allergic reactions accompanied by rash, itching and hives, symptoms of fever, swollen joints and joint pain, muscle pain, symptoms of swollen lymph nodes and/or flu-like symptoms may occur (signs of serum sickness)
- Purplish-red spots, fever, itching (signs of inflammation of the blood vessels also called vasculitis)
- Unusual bleeding or bruising (signs of thrombocytopenia - low level of blood platelets)
- Muscle pain (myalgia)
- Fever, sore throat or mouth ulcers resulting from infections (symptoms of a low level of white blood cells, called neutropenia)
- Decrease in level of hemoglobin and decrease in the percentage of red blood cells in the blood (which can, in severe cases, lead to anemia)
- Increase in levels of potassium in the blood (which can, in severe cases, trigger muscle spasms and irregular heart rhythm)
- Elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can, in severe cases, cause yellowing of the skin and eyes)
- Increase in level of blood urea nitrogen and increase in level of serum creatinine (which can indicate abnormal kidney function)
- Low levels of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases)

The frequency of some side effects may vary depending on your condition. For example, side effects such as dizziness and decreased kidney function, were seen less frequently in patients treated for high blood pressure than in patients treated for heart failure or after a recent heart attack.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

Side effects can also be reported to Novartis company via the email address: safetydesk.israel@novartis.com

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:

Store below 25°C. Store in the original packaging in order to protect from moisture.

Do not store different medicines in the same package. Do not use if the package is damaged.

Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines that are no longer needed. This is in order to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose, crospovidone, magnesium stearate, colloidal anhydrous silica.

The tablet coating contains: Hypromellose, titanium dioxide (E171), macrogol 8000, iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172) (only 40 mg and 160 mg).

What the medicine looks like and the contents of the package:

Diovan 40 mg film-coated tablets: A yellow, oval tablet with beveled edges, with a score line on one side, with "D" and "O" debossed on either side of the score line and "NVR" on the other side of the tablet.

The tablet can be divided into two equal doses.

Package size: 14 or 28 tablets (not all pack sizes may be marketed).

Diovan 80 mg film-coated tablets: Pale red, round tablet, with beveled edges, with a score line on one side, with "D" and "V" debossed on either side of the score line and "NVR" on the other side of the tablet.

To ease swallowing, if needed, the tablet can be halved for immediate use. Swallow both halves together immediately after splitting.

Package size: 14, 28, 56 or 98 tablets (not all pack sizes may be marketed).

Diovan 160 mg film-coated tablets: Grey-orange, ovaloid, slightly convex tablet, with a score line on one side debossed with "DX" on either side of the score line and "NVR" on the other side of the tablet.

To ease swallowing, if needed, the tablet can be halved for immediate use. Swallow both halves together immediately after splitting.

Package size: 14, 28, 56 or 98 tablets (not all pack sizes may be marketed).

Registration Holder and Importer and its address: Novartis Israel Ltd., P.O.B. 9240, Tel Aviv.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Diovan 40 mg film-coated tablets: 137 42 31281

Diovan 80 mg film-coated tablets: 127 85 30548

Diovan 160 mg film-coated tablets: 127 86 30549