

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

The medicine is dispensed with a doctor's prescription only

Vector 80, 160 Tablets

Composition:

Each film-coated tablet of **Vector 80** contains: Valsartan 80 mg

Each film-coated tablet of **Vector 160** contains: Valsartan 160 mg

For the list of inactive and allergenic ingredients in the preparation, see section 6 "Further information" and section 2 "Before using the medicine".

Read the 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?

For the treatment of hypertension. For the treatment of heart failure. For treatment after myocardial infarction.

Hypertension increases the workload of the heart and the arteries. If this continues over time, it can cause damage to the blood vessels of the brain, the heart and the kidneys, and can lead to stroke, heart failure or kidney failure. Hypertension increases the risk of heart attacks. Lowering blood pressure to normal levels reduces the risk of these problems developing.

Heart failure is associated with shortness of breath and swelling of the feet and legs due to fluid accumulation. Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood required by the body.

Vector can be used to treat people following a heart attack (myocardial infarction) in order to improve survival and to reduce further heart problems.

If you have questions about how **Vector** works or why this medicine has been prescribed for you, ask the doctor.

Therapeutic group: Angiotensin II antagonist.

Vector belongs to a group of medicines called angiotensin II receptor antagonists which help control hypertension. Angiotensin II is a substance found in the body that causes the blood vessels to constrict, thereby making the blood pressure rise. **Vector** acts by blocking the effect of angiotensin II. As a result, the blood vessels relax and the blood pressure drops.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient valsartan, or to any of the additional ingredients contained in the medicine (see section 6: "Further information").
- You suffer from a severe liver function disturbance.

- You are more than three months pregnant (it is also preferable to avoid taking **Vector** at the beginning of pregnancy; see section "Pregnancy and breastfeeding").
- You are being treated with a blood pressure-lowering medicine containing aliskiren because you have diabetes or are suffering from impaired kidney function.

If any of these conditions apply to you, inform the doctor without taking Vector.

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

- You have a liver disease.
- You have a serious kidney disease or 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 you get these symptoms while taking Vector, stop taking Vector immediately and never take Vector again.** See also section 4, "Side effects".
- You are taking medicines that increase blood potassium levels. 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 an excess of the hormone aldosterone. In this case, it is not recommended to use **Vector**.
- You have lost a large amount of fluids (dehydration) due to diarrhea and vomiting or high doses of diuretics.
- You are taking any of the following medicines used to treat hypertension:
 - An ACE (angiotensin converting enzyme) medicine (e.g., enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
 - Aliskiren.
 - If you are taking an ACE inhibitor in combination with other medicines to treat your heart failure, known as mineralocorticoid receptor antagonists (MRAs) (with blocking activity) (e.g., spironolactone, eplerenone) or beta blockers (e.g., metoprolol).

Also review information in section "Do not use the medicine if".

Tell the doctor if you think you are (or might be) pregnant. Taking **Vector** is not recommended in the early stages of pregnancy. **Do not take Vector** if you are more than three months pregnant, as serious harm could be caused to the unborn child if you use the medicine at this stage (see "Pregnancy and breastfeeding" section).

Children:

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

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.

Drug interactions: **If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** The treatment may be affected if **Vector** is taken together with certain medicines.

It may be necessary to change the dosage, take precautionary measures, 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 to lower blood pressure, especially diuretics, ACE inhibitors (such as enalapril, lisinopril) 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 the blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin.
- A certain type of painkiller called non-steroidal anti-inflammatory drugs (NSAIDs).
- Some antibiotics (from the rifampicin group), such as a medicine used to protect against transplant rejection (cyclosporin) or an antiretroviral medicine used to treat HIV/AIDS infection (ritonavir). These medicines may increase the effect of **Vector**.
- Lithium**, a medicine used to treat some 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 with a triple combination of 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) – **this combination is not recommended.**

Use of the medicine and food:

Vector may be taken with or without food.

Pregnancy and breastfeeding:

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

The doctor will likely advise you to stop taking **Vector** before you become pregnant or immediately after you find out you are pregnant; he will advise you to take another medicine instead of **Vector**. **Vector** is not recommended in the early stages of pregnancy, and **must not** be taken from the end of the third month of pregnancy, as it may cause severe harm to the unborn baby and/or your baby if you used it after the third month of pregnancy.

- Tell your doctor if you are breastfeeding or planning to start breastfeeding.** **Vector** is not recommended for breastfeeding mothers and your doctor will likely choose a different treatment for you if you want to breastfeed, especially if your baby was just born or is premature.

Driving and using machinery:

Before driving a vehicle, using machinery or performing any activity that requires concentration, make sure you know how you react to **Vector**. As with many other medicines

used to treat hypertension, **Vector** may cause dizziness and impair concentration.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use 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 the medicine was prescribed.

Vector can be used in patients aged 65 and over. This medicine is not intended for infants, children and adolescents under the age of 18.

Do not exceed the recommended dosage.

Generally, patients with hypertension do not notice any symptoms of the problem. Many feel well. Therefore, it is very important to keep your appointments with the doctor even if you are feeling well.

Method of administration: **Use this medicine at specific time intervals as determined by the attending doctor.**

It is advisable to take the medicine at the same time each day, preferably in the morning. Taking the medicine at the same time each day will help you remember when to take the medicine.

Swallow the medicine with a glass of water. The medicine can be taken with or without food. If necessary, the tablet can be halved, for immediate use. There is no information regarding crushing or chewing the tablet.

If you accidentally take a higher dose

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 Vector

If you forgot to take a dose, take it as soon as you remember. If it is almost time to take the next dose, skip the forgotten dose. Do not take a double dose. Take the next dose at the regular 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, since it may make your illness worse. 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 **Vector** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Some side effects can be serious and require 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 Vector 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 in 10 users):

- Dizziness
- Low blood pressure, with or without symptoms such as: dizziness and fainting when standing up
- Decreased kidney function (symptoms of kidney impairment).

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

- Allergic reaction (angioedema) see section "Special warnings regarding use of the medicine". Refer to the doctor immediately for medical assistance
- Sudden loss of consciousness (fainting)
- Spinning sensation (vertigo)
- Severe reduction in kidney function (symptoms of acute kidney failure)
- Muscle spasms, abnormal heart rhythm (symptoms of hyperkalemia – excess potassium)
- Shortness of breath, difficulty breathing while lying down, swelling of the legs or feet (symptoms of heart failure)
- Headache
- Cough
- Abdominal pain
- Nausea
- Diarrhea
- Fatigue
- Weakness

Side effects of unknown frequency (frequency can not be assessed from the available data)

- Blistering skin (symptom of dermatitis bullous)
- Allergic reactions accompanied by rash, itching and urticaria, together with some of the following symptoms: fever, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms (symptoms of serum sickness)
- Purplish-reddish spots, fever, itching (symptoms of inflammation in the blood vessels, also called vasculitis)
- Unusual bleeding or bruising (symptoms of thrombocytopenia – low level of platelets)
- Muscle pain (myalgia)
- Fever, sore throat or mouth ulcers due to infections (symptoms of a low level of white blood cells called neutropenia)
- Decreased hemoglobin level and decreased 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 the eyes)
- An increase in the level of urea nitrogen in the blood and an increase in the level of creatinine in the serum (which can indicate abnormal kidney function)
- Low levels of sodium in the blood (may cause tiredness, confusion, muscle twitching and/or spasms 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 hypertension 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 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.

Additionally, you can report to "Unipharm Ltd.".

5. HOW TO STORE THE MEDICINE?

- 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 a 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.
- Store at a temperature below 25°C, in a place protected from light.
- Do not discard medicines in the wastewater or household waste bin. Consult the pharmacist about how to dispose of medicines that are no longer needed. These measures will help protect the environment.

6. FURTHER INFORMATION

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

Lactose monohydrate, Microcrystalline cellulose, Crospovidone, Magnesium stearate, Colloidal silicon dioxide, Opadry (white, yellow, orange).

Each film-coated tablet of **Vector 80** contains 91 mg lactose monohydrate.

Each film-coated tablet of **Vector 160** contains 182 mg lactose monohydrate.

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

Vector is packaged in trays (blisters) inserted in a carton box.

Each package has 7, 14, 28, 30, 56 or 60 tablets.

Not all package sizes may be marketed.

Vector are round, film-coated, biconvex, yellow tablets, with a score line on one side.

Registration holder and address: Unipharm Ltd., P.O.Box 21429, Tel Aviv, 6121301.

Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.

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

Vector 80: 145 43 33075 01

Vector 160: 145 44 33076 01

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