

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

This medicine is dispensed with  
a doctor's prescription only

## Vector 80, 160

### Film-coated 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 a list of inactive ingredients, please see 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.

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

#### 1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of hypertension. For treatment of heart failure. For treatment following 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 accumulation of fluids. Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood required to 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, thus making the blood pressure rise. **Vector** acts by blocking the effect of angiotensin II. As a result, the blood vessels relax and blood pressure is lowered.

#### 2. BEFORE USING THE MEDICINE

##### ☒ Do not use the medicine if:

- You are in the third, or later, month of pregnancy (it is also preferable to avoid taking valsartan at the beginning of pregnancy; see section "Pregnancy and breastfeeding").
  - You are sensitive (allergic) to valsartan or to any of the additional ingredients contained in the medicine (see section 6: "Further information"). If you think you are allergic, refer to the doctor for advice.
  - You suffer from severe liver dysfunction, cirrhosis or biliary obstruction.
  - You have a high level of sugar in the blood and you are suffering from diabetes and you are taking a blood pressure-lowering medicine containing aliskiren (such as: Rasilez) at the same time.
  - You are suffering from kidney function impairment and you are taking a blood pressure-lowering medicine containing aliskiren (such as: Rasilez) at the same time.
- If any of these conditions apply to you, **tell your 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 taking an ACE inhibitor (such as enalapril, lisinopril, ramipril) together with a beta-blocker medicine (a beta blocker such as metoprolol) or an ACE inhibitor together with an MRA type medicine (a medicine that blocks receptors for mineralocorticoids) such as spironolactone, eplerenone for treating heart failure.
- You are suffering from vomiting or diarrhea or are taking high doses of diuretics.
- You suffer from heart failure or have had a myocardial infarction. Follow the doctor's instructions exactly regarding the starting dosage. The doctor may check your kidney function.
- You have ever had swelling, mainly of the face and throat, while taking other medicines (including an ACE inhibitors). If you get these symptoms, **stop taking Vector and contact the doctor immediately. You should never take Vector again (see section 4 "Side effects")**.
- You are taking medicines that increase the levels of potassium in your blood, e.g., potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium and heparin. It may be necessary to perform periodic tests of blood potassium levels.
- You suffer from aldosteronism (a disease where the adrenal gland produces too much aldosterone). In this case, it is not recommended to take **Vector**.

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutrition supplements, tell the doctor or pharmacist.**

It may be necessary to change the dosage, take precautionary measures, or in some cases to stop taking one of the medicines. Especially inform the doctor or pharmacist if you are taking the following medicines:

- Medicines used to lower blood pressure, especially diuretics, ACE inhibitors (such as: enalapril, lisinopril) or aliskiren (see section 2 "Do not use the medicine if" and "Special warnings regarding use of the medicine").
- Potassium-sparing diuretics such as: spironolactone, triamterene, amiloride, potassium supplements or salt substitutes containing potassium. The doctor may perform periodic tests of your blood potassium levels.
- A certain type of painkillers called non-steroidal anti-inflammatory drugs (NSAIDs) or selective cyclooxygenase-2 inhibitors (COX-2 inhibitors). The doctor may also check your kidney function.
- Lithium (a medicine used to treat some types of psychiatric illness).
- Some antibiotics (rifamycin group), 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**.

##### ☒ Additional medicines:

- Combination with an ACE inhibitor and a beta blocker medicine (such as metoprolol) to treat heart failure is not recommended.
- Combination with an ACE inhibitor and medicines from the MRA group (such as spironolactone, eplerenone).
- Combination with an ACE inhibitor for treatment following a heart attack is not recommended.

##### ☒ Use of the medicine and food:

**Vector** may be taken with or without meal.

##### ☒ Pregnancy and breastfeeding:

Tell the doctor if you are pregnant or think that you may be pregnant. The doctor will normally advise you to stop taking the medicine before you become pregnant or immediately after you know you are pregnant, and to take another medicine instead of **Vector**. The medicine is not recommended in early stages of pregnancy, and is forbidden for use after the third month of pregnancy and onwards, as it may cause severe harm to your baby if taken after the third month of pregnancy.

Consult with your doctor if you are breastfeeding or planning to breastfeed.

Breastfeeding newborns (in the first weeks after delivery), especially premature babies, is not recommended when taking the medicine.

##### ☒ Driving and using machinery:

As with many other medicines used to treat hypertension, **Vector** may in rare cases cause dizziness and impairment of concentration.

Therefore, before driving a vehicle, operating machinery or carrying out any activity that requires concentration, make sure you know how you react to **Vector**.

##### ☒ Important information about some of the ingredients of the medicine:

This medicine contains lactose. If you have been told by your doctor that you suffer from intolerance to certain sugars, contact your doctor before taking the medicine.

#### 3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure.

The dosage and treatment regimen will be determined by the doctor only.

##### Do not exceed the recommended dose.

Generally, patients with hypertension do not notice any signs of the problem. Many feel well. Therefore, it is very important to keep your appointments with the doctor even if you are feeling well. It is important that you take this medicine exactly as instructed by your doctor in order to get the best results and reduce the risk of side effects. **Vector** can be used in patients 65 years of age and older.

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

This medicine is to be taken 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 a meal. The tablet can be halved – for immediate use. There is no information regarding crushing or chewing the preparation.

If you accidentally took a higher dose, effects are possible, such as: dizziness and/or fainting. 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 this medicine at the required time, do not take a double dose. Take the next dose at the regular time and consult the doctor.

Adhere to the treatment regimen 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 treatment with the medicine may make your illness worse. Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine or about how long to take **Vector**, 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 by the list of side effects. You may not suffer from any of them.

**Refer to the doctor immediately** if you have symptoms of angioedema (allergic reaction) such as: swelling of the face, lips, tongue or throat, difficulty breathing, urticaria, difficulty swallowing.

##### Additional side effects:

**Common side effects (effects that occur in 1-10 in 100 users):** dizziness; low blood pressure with symptoms such as dizziness; decreased kidney function (signs of a kidney disorder).

**Uncommon side effects (effects that occur in 1-10 in 1,000 users):** allergic reaction with symptoms such as rash, itching, dizziness, swelling of the face, lips, tongue and/or throat, difficulty breathing or swallowing (signs of angioedema) - see also: "Refer to the doctor immediately if"; sudden loss of consciousness; spinning feeling; severe reduction in kidney function (signs of acute kidney failure); muscle spasms, abnormal heart rhythm (signs of hyperkalemia); shortness of breath, difficulty breathing while lying down, swelling of the legs or feet (signs of heart failure); headache; cough; abdominal pain; nausea; diarrhea; fatigue; weakness.

**Side effects reported (their frequency is not known):** blistering skin (sign of dermatitis bullous); rash, itching, together with some of the following signs or symptoms: fever, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms (signs of serum sickness); purplish-reddish spots, fever, itching (signs of inflammation of blood vessels); unusual bleeding or bruising (signs of low level of platelets); muscle pain (myalgia); fever, sore throat or mouth ulcers due to infections (symptoms of low levels of white blood cells); decrease of hemoglobin levels and decrease of 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 abnormal 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 eyes and skin); increase in the level of blood urea nitrogen and increase in the level of serum creatinine (which can indicate abnormal kidney function). Low levels of sodium in the blood (may cause tiredness, confusion, muscle spasms and/or seizures 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.

The following effects have been observed during clinical trials with valsartan without the possibility to determine if they were caused by the medicine or by other causes: back pain, changes in libido, inflammation of the sinuses, insomnia, joint pain,

pharyngitis, runny or stuffy nose, swelling of the hands, heels or feet, upper respiratory tract infections, viral infections.

If a side effects occurs, if one of the side effects worsens, or when 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](http://www.health.gov.il)) that directs you to the online form for reporting side effects. Alternatively, 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 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 temperature below 25°C, in a place protected from light.
- Do not store different medications in the same package.

#### 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 content of the package:

**Vector** is packaged in trays (blisters) inserted in a carton box. Each package contains 28 tablets.

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

Name of registration holder: Unipharm Ltd., P.O.B. 21429, Tel Aviv, 6121301.

Name of manufacturer and address: Trima Ltd., Kibbutz Maabarot.

This leaflet was checked and approved by the Ministry of Health in November 2016.

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

**Vector 80:** 145 43 33075 00

**Vector 160:** 145 44 33076 00