

Use in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

VECTOR PLUS

80/12.5

Film-coated tablets

Composition:

Each tablet contains:
Valsartan 80 mg
Hydrochlorothiazide 12.5 mg

VECTOR PLUS

160/12.5

Film-coated tablets

Composition:

Each tablet contains:
Valsartan 160 mg
Hydrochlorothiazide 12.5 mg

VECTOR PLUS

160/25

Film-coated tablets

Composition:

Each tablet contains:
Valsartan 160 mg
Hydrochlorothiazide 25 mg

Inactive ingredients: See section 6: ‘Additional information’.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?
For the treatment of hypertension in patients who need combined therapy with two active ingredients.

Vector Plus contains two active ingredients called valsartan and hydrochlorothiazide. Both of these components help to control high blood pressure (hypertension).

- Valsartan** belongs to a group of medicines known as “angiotensin II receptor antagonists” (blocking the receptor), which help to control high blood pressure. Angiotensin II is a substance in your body that causes blood vessels to tighten, and this causes your blood pressure to rise. Valsartan works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.
- Hydrochlorothiazide** belongs to a group of medicines called thiazide diuretics. Hydrochlorothiazide increases urine output, which helps to lower blood pressure.

Vector Plus is used to treat high blood pressure which is not adequately controlled by a single substance alone.

High blood pressure increases the workload of the heart and arteries. If not treated, 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.

Therapeutic group: A combination of an angiotensin II receptor antagonist with a thiazide diuretic.

2. Before using this medicine

❗ Do not use this medicine if:

- you are sensitive (allergic) to valsartan, hydrochlorothiazide, sulfonamide derivatives (substances chemically related to hydrochlorothiazide) or to any of the other ingredients in this medicine (listed in section 6)
- you are more than 3 months pregnant (it is also better to avoid **Vector Plus** in early pregnancy - see the section ‘**Pregnancy, breastfeeding, and fertility**’)
- you have severe liver disease with destruction of the small bile ducts within the liver (biliary cirrhosis) leading to build-up of bile in the liver (cholestasis)
- you are unable to produce urine (anuria)
- the levels of potassium or sodium in your blood are lower than normal, or the level of calcium in your blood is higher than normal despite treatment
- you have gout
- you have diabetes or impaired kidney function (GFR<30ml/min/1.73m²) and you are being treated with a blood pressure lowering medicine containing aliskiren

If any of the above apply to you, inform your doctor and do not take Vector Plus.

Special warnings about using this medicine:

❗ Before taking Vector Plus, tell your doctor if:

- you are taking potassium-sparing medicines, potassium supplements, salt substitutes containing potassium or other medicines that increase the amount of potassium in your blood such as heparin. Your doctor may check the levels of potassium in your blood regularly
- you have low levels of potassium in your blood
- you have diarrhea or severe vomiting
- you are taking high doses of diuretics
- you have severe heart disease
- you have heart failure or have experienced a heart attack. Carefully follow your doctor’s instructions for the starting dose. Your doctor may also check your kidney function
- you have a narrowing of the kidney artery
- you have recently had a kidney transplant
- you have a disease called hyperaldosteronism. This is a disease in which your adrenal glands make too much of the hormone aldosterone. If this applies to you, the use of **Vector Plus** is not recommended

- you have liver or kidney disease
- you have ever experienced swelling of the tongue and face caused by an allergic reaction called angioedema when taking other medicines (including ACE inhibitors), tell your doctor. If these symptoms occur when you are taking **Vector Plus, stop taking Vector Plus immediately and never take Vector Plus again.** See section 4: ‘**Side effects**’
- you have fever, rash, and joint pain, which may be signs of systemic lupus erythematosus (an autoimmune disease)
- you have diabetes, gout, high levels of cholesterol or triglycerides in your blood
- you have had an allergic reaction with the use of other blood pressure-lowering medicines of the same type (angiotensin II receptor antagonists) or if you have allergy or asthma

- you experience eye pain or a decrease in vision. These could be symptoms of increased pressure in your eye that can happen within hours to a week of taking **Vector Plus**. This can lead to permanent vision loss, if not treated. If you have ever had an allergy to penicillin or sulfonamide you are at a high risk of developing this effect
- you are taking any of the following medicines used to treat high blood pressure:**
 - ACE inhibitors (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems - aliskiren
 - you have ever had skin cancer or if you develop an unexpected skin lesion while using this medicine. Using hydrochlorothiazide may increase your risk of developing skin or lip cancer (a type of skin cancer that is not melanoma), particularly with long-term use of high doses

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 - you have ever had skin cancer or if you develop an unexpected skin lesion while using this medicine. Using hydrochlorothiazide may increase your risk of developing skin or lip cancer (a type of skin cancer that is not melanoma), particularly with long-term use of high doses
- Protect your skin from exposure to the sun and ultraviolet (UV) rays while using **Vector Plus**.

Vector Plus may cause increased sensitivity of the skin to sun.

Tell your doctor if you think you are (or might become) pregnant. **Vector Plus** is not recommended in early pregnancy, and must not be taken when more than three months pregnant, as it may cause serious harm to your baby if it is used during this stage of pregnancy (see the section ‘**Pregnancy, breastfeeding, and fertility**’).

Tests and follow-up:

Your doctor may refer you to tests for kidney function, blood pressure, and the levels of electrolytes (e.g. potassium) in your blood regularly during the course of this treatment. See additional information under the section ‘**Do not use this medicine if**’.

Children and adolescents: Use of **Vector Plus** in children and adolescents (under 18 years old) is not recommended.

❗ Other medicines and Vector Plus

If you are taking or have recently taken

other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist. The effect of the treatment can be influenced if **Vector Plus** is taken together with certain other medicines. It may be necessary to change your dose, to take other precautions, or in some cases to stop taking one of the medicines. In particular, tell your doctor or pharmacist if you are taking medicines that belong to any of the following groups:

- lithium, a medicine used to treat some types of psychiatric disorders
- medicines or substances that may increase the levels of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium sparing medicines, and heparin
- medicines that may reduce the levels of potassium in your blood such as diuretics, corticosteroids, laxatives, carbenoxolone, amphotericin, or penicillin G
- certain antibiotics (rifamycin group), medicine used to protect against transplant rejection (cyclosporine) or an antiretroviral medicine used to treat HIV/AIDS infection (ritonavir). These medicines may increase the effect of **Vector Plus**
- medicines that may cause heart rhythm disorders such as antiarrhythmics (medicines used to treat heart problems) and antipsychotics
- medicines that may reduce the levels of sodium in your blood, such as antidepressants, antipsychotics, and antiepileptics
- medicines for the treatment of gout, such as allopurinol, probenecid, sulfipyrazone
- vitamin D and calcium supplements
- medicines for the treatment of diabetes (oral agents like metformin, or insulin injections)
- other medicines for lowering blood pressure, including methyl dopa, ACE inhibitors (such as enalapril, lisinopril) or aliskiren (see additional information under the headings ‘**Do not use this medicine if**’ and ‘**Special warnings about using this medicine**’)
- medicines that raise your blood pressure such as noradrenaline or adrenaline
- digoxin or other digitalis glycosides (medicines used to treat heart problems)
- medicines that may increase blood sugar levels, such as diazoxide or beta blockers
- cytotoxic medicines (used to treat cancer), such as methotrexate or cyclophosphamide
- pain killers such as non-steroidal anti-inflammatory medicines (NSAIDs), including selective cyclooxygenase-2-inhibitors (COX-2 inhibitors) and acetylsalicylic acid (aspirin) over 3g
- muscle relaxing medicines, such as tubocurarine
- anti-cholinergic medicines (medicines used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson’s disease

and as an aid to anesthesia)

- amantadine (a medicine used to treat Parkinson’s disease and treat or prevent certain viral diseases)
- colestyramine and colestipol (medicines used mainly to treat high levels of fats in the blood)
- cyclosporine, a medicine used for organ transplant to prevent organ rejection
- alcohol, sleeping pills and anesthetics (medicines with sleeping or painkilling effect used for example during surgery)
- iodine contrast media (substances used for imaging examinations)

❗ Using Vector Plus and alcohol

consumption:

Avoid drinking alcohol until you have talked to your doctor. Alcohol may make your blood pressure fall more and/or may increase your risk of getting dizzy or fainting.

❗ Using Vector Plus and food:

You can take this medicine with or without food.

❗ Pregnancy, breastfeeding, and fertility:

- You must tell your doctor if you think that you are (or might become) pregnant.** Your doctor will advise you to stop taking **Vector Plus** before you become pregnant or as soon as you know you are pregnant, and will advise you to use a different treatment instead of **Vector Plus**. **Vector Plus** is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if it is used after the third month of pregnancy.
- Tell your doctor if you are breastfeeding or plan to breastfeed.**

Vector Plus is not recommended during breastfeeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is newborn, or was born prematurely.

❗ Driving and using machines:

Before you drive a vehicle, use tools or operate machines, or carry out other activities that require concentration, make sure you know how **Vector Plus** affects you. Like many other medicines used to treat high blood pressure, **Vector Plus** may occasionally cause dizziness and affect your ability to concentrate.

Important information about some of this medicine’s ingredients:

This medicine contains lactose (see section 6: ‘Additional information’). If you have been told by your doctor that you have an intolerance to certain sugars, consult your doctor before taking this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor’s instructions. This will help you to get the best results and lower the risk of side effects. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. People with 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 your doctor even if you are feeling well. Only your doctor will determine your dose and how you should take this medicine. Your doctor will tell you how many tablets of **Vector Plus** to take.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose of medicine.

- The recommended dose of **Vector Plus** is one tablet once a day
- Do not change the dose or stop taking the medicine without consulting your doctor
- Take this medicine at the same time each day, preferably in the morning hours
- You can take **Vector Plus** with or without food
- Swallow the tablet with a glass of water
- If necessary, you may split the tablet immediately before taking it. There is no information about crushing or chewing the tablet

Do not exceed the recommended dose.

If you have accidentally taken a higher dose

If you experience severe dizziness and/or fainting, lie down and contact your doctor **immediately**. If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take Vector Plus

If you forget to take your dose at the scheduled time, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose. Take the next dose at the usual time and consult your doctor. Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking this medicine

Stopping your treatment with **Vector Plus** may cause your high blood pressure to get worse. Do not stop taking your medicine unless your doctor tells you to.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them. If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using **Vector Plus** may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Some side effects can be serious and need immediate medical attention: Consult your doctor immediately if:

- you experience any symptoms of angioedema, such as:
 - swollen face, tongue or throat
 - difficulty in swallowing
 - hives and difficulty in breathing
- severe skin disease that causes rash,

skin redness, blistering of the lips, eyes or mouth, skin peeling, fever (toxic epidermal necrolysis)

- decrease in vision or pain in your eyes due to high blood pressure (possible signs of acute angle-closure glaucoma)
- fever, sore throat, more frequent infections (agranulocytosis)

These are very rare side effects and their frequency is not known.

If you notice any of these symptoms, stop taking Vector Plus and consult your doctor immediately (see under the section ‘**Special warnings about using this medicine**’).

Additional side effects:

Uncommon side effects (may affect up to 1 in 100 users):

Cough; low blood pressure; light-headedness; dehydration (with symptoms such as thirst, dry mouth and tongue, low urine output, dark colored urine, dry skin); muscle pain; tiredness; tingling or numbness; blurred vision; noises (hissing, buzzing) in ears.

Very rare side effects (may affect up to 1 in 10,000 users):

Dizziness; diarrhea; joint pain.

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

Breathing difficulty; severely decreased urine output; low levels of sodium in the blood (may induce tiredness, confusion, muscle spasms and/or convulsions in acute cases); low levels of potassium in the blood (sometimes with muscle weakness, muscle spasms, abnormal heart rhythm); low levels of white blood cells (with symptoms such as fever, skin infections, sore throat or mouth-ulcers due to infections, weakness); increase in levels of bilirubin in your blood (which can, in severe cases, cause yellow skin and eyes); increase in the levels of urea nitrogen (BUN) and creatinine in blood (may indicate impaired kidney function); increase in the levels of uric acid in your blood (which can, in severe cases, trigger gout); fainting.

The following side effects have been reported with other products which contain valsartan or hydrochlorothiazide alone:

Valsartan:

Uncommon side effects (may affect up to 1 in 100 users):

Spinning sensation; abdominal pain.

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

Blisters on the skin (sign of bullous skin inflammation [dermatitis]); skin rash with or without itching together with some of the following signs or symptoms: fever, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms; rash, purplish-red spots, fever, itching (symptoms of inflammation of blood vessels); low level of blood platelets (sometimes with unusual bleeding or bruising); high levels of potassium in the blood (sometimes with

muscle spasms, abnormal heart rhythm); allergic reaction (with symptoms such as rash, itching, hives, difficulty breathing or swallowing, dizziness); swelling mainly of the face and throat, rash, itching; elevation of liver function values; decrease in the levels of hemoglobin and the percentage of red blood cells in the blood (both can, in severe cases, cause anemia); kidney failure; low levels of sodium in the blood (may induce tiredness, confusion, muscle spasms and/or convulsions in acute cases).

Hydrochlorothiazide:

Very common side effects (may affect more than 1 in 10 users):

Low levels of potassium in the blood; increase of lipids in the blood.

Common side effects (may affect up to 1 in 10 users):

Low levels of potassium in the blood; low levels of magnesium in the blood; high levels of uric acid in the blood; itchy rash or other types of rash; reduced appetite; mild nausea and vomiting; dizziness, fainting on standing up; inability to achieve or maintain an erection.

Rare side effects (may affect up to 1 in 1,000 users):

Swelling and blistering of the skin (due to increased sensitivity to sun); high levels of calcium in the blood; high levels of sugar in the blood; sugar in the urine; worsening of diabetic metabolic state; constipation, diarrhea, abdominal discomfort, liver disorder which may occur with yellowing of the skin and eyes); irregular heart beat; headache; sleep disturbances; sad mood (depression); low levels of blood platelets (sometimes with bleeding or bruising underneath the skin); dizziness; tingling or numbness; vision disturbances.

Very rare side effects (may affect up to 1 in 10,000 users):

Infection of blood vessels with symptoms such as rash, purplish-red spots, fever (vasculitis); rash, itching, hives, difficulty breathing and swallowing, dizziness (hypersensitivity reactions); facial rash, joint pain, muscle disorder, fever (possible signs of cutaneous lupus erythematosus); severe upper stomach pain (pancreatitis); difficulty breathing with fever, coughing, wheezing, breathlessness (respiratory distress including pneumonia and pulmonary edema); pale skin, tiredness, breathlessness, dark urine (possible signs of hemolytic anemia); fever, sore throat or ulcers due to infections (leucopenia); confusion, tiredness, muscle twitching and spasms, rapid breathing (possible signs of alkalosis as a result of low levels of chlorine in the blood).

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

Weakness, bruising, and frequent infections (aplastic anemia); severely decreased urine output (possible signs of kidney disorder or kidney failure); rash, skin redness, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of erythema multiforme); muscle spasm; fever (pyrexia); weakness; cancer of the skin and lips (skin cancer that is not melanoma).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link ‘Reporting Side Effects of Drug Treatment’ on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

In addition, you can also report to **Unipharm Ltd.**

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store in a dry place below 25°C.
- Do not use if the medicine’s package is damaged.

Do not discard the tablets in the drain or your household waste. Ask your pharmacist how to dispose of medicines you no longer need. This will help protect the environment.

6. Additional information

In addition to the active ingredients, this medicine also contains: lactose monohydrate, microcrystalline cellulose, crospovidone, magnesium stearate, colloidal silicon dioxide, Opadry (orange, yellow).

What the medicine looks like and contents of the pack:

Vector Plus is packaged in blister trays placed in a cardboard box. Each pack contains 28 tablets.

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

Vector Plus is available in pack sizes of 5, 10, 14, 15, 20, 28, and 30 tablets.

Not all pack sizes may be marketed.

Registration holder: Unipharm Ltd., POB 21429, Tel Aviv 6121301.

Manufacturer: Unipharm Ltd., Mevo Carmel Industrial Park.

This leaflet, dated January 2020, is formatted according to Ministry of Health guidelines and its content matches the original medicinal product leaflet reviewed and approved by the Ministry of Health in March 2019.

Registration number of the medicine in the Ministry of Health’s National Drug Registry: **VECTOR PLUS 80/12.5:** 145 06 33145 01 **VECTOR PLUS 160/12.5:** 146 06 33406 01 **VECTOR PLUS 160/25:** 145 07 33146 01