

VALEZTO FILM-COATED TABLET

Amlodipine & Valsartan (5mg/80 mg & 10mg/160mg)

What is in this leaflet

1. What Valezto is used for
2. How Valezto works
3. Before you use Valezto
4. How to use Valezto
5. While you are using it
6. Side effects
7. Storage and Disposal of Valezto
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP Revision

What Valezto is used for

Your medicine is called Valezto and is available as a film-coated tablet.

Valezto contains amlodipine, a medicine that belongs to the class of calcium antagonists and valsartan, which belongs to angiotensin-II receptor antagonists. They both help to control high blood pressure.

Valezto is indicated to treat high blood pressure which is not adequately controlled by a single drug.

How Valezto works

Amlodipine blocks calcium channels at the blood vessels. Angiotensin II is a natural substance produced by the body that causes blood vessels to tighten, thus increasing the blood pressure. Valsartan works by blocking the effect of angiotensin II. As a result of both mechanisms, blood vessels relax and blood pressure is lowered.

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

Before you use Valezto

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

When you must not use it

Do not take this medicine:

- If you are allergic to amlodipine or valsartan or any other ingredients of this medicine (listed in Product Description)
- 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 you have severe liver impairment; biliary cirrhosis (blocking of bile ducts in the liver) and cholestasis (bile cannot flow from liver to intestine).

If any of these apply to you, tell your doctor before taking Valezto.

Before you start to use it

Check with your doctor or pharmacist before taking Valezto:

- If you are suffering from several episodes of vomiting or diarrhea or are taking a diuretic (a drug increasing the amount of urine).
- If you are taking other drugs or substances, which increase the potassium levels in your blood (such as certain types of diuretics, potassium supplements, etc.).
- If you suffer from liver or severe kidney problems.
- If your doctor has diagnosed that you are suffering from a narrowing of valves in your heart (called aortic or mitral stenosis), or abnormally increased thickness of your heart muscle with narrowing (called obstructive hypertrophic cardiomyopathy).
- If you ever had a swelling mainly of the face and throat while taking other medicines (including an ACE-inhibitor). If you get those symptoms, stop taking Valezto and contact your doctor immediately. You should never take Valezto again.
- 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 are treated with an ACE-inhibitor or aliskiren

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

Also tell your doctor if you have received a kidney transplant or if you had been diagnosed to suffer from a narrowing of your kidney artery.

Pregnancy and lactation

Do not take Valezto if you are pregnant or planning to become pregnant. Use

during pregnancy has been associated with serious damage to your unborn child.

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

Your doctor will discuss with you the potential risk of taking Valezto during pregnancy.

Tell your doctor if you are breast-feeding. Treatment with Valezto is not recommended during breast-feeding.

Older people (aged 65 years and over)

There are no special dose recommendations for patients aged 65 years or older.

Children and adolescents

The use of Valezto in children and adolescents is not recommended.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

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 medicines both prescribed and not prescribed by a doctor.

Inform your doctor or pharmacist if you are taking:

- Medicines used to lower blood pressure, especially diuretics (water pills), ACE-inhibitors or aliskiren;
- Potassium-sparing medicines, potassium supplements, or salt substitutes containing potassium. 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.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines that can change the amount of amlodipine in your body, especially:

- Medicines used to prevent and treat fungal skin infections (such as Ketoconazole, itraconazole)
- Medicines used to treat AIDS or HIV infections (such as Ritonavir, indinavir)
- Medicines used to treat bacterial infections (such as clarithromycin, talithromycin, rifampicin)
- Simvastatin, (a medicine used to control elevated cholesterol)
- Medicines used to treatment for depression (such as St. John's wort, hypericum perforatum)

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines that can change the amount of valsartan in your body, especially

- Some antibiotics (rifamycin group), medicines used to protect against transplant rejection (ciclosporin) or an antiretroviral medicine used to treat HIV/AIDS infection (ritonavir). These medicines may increase the effect of valsartan

How to use Valezto

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help. Valezto is for oral use only.

Do not exceed the recommended dose. Swallow the tablets with a glass of water.

How much to use

Your doctor will tell you exactly how many tablets of Valezto you should take.

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

The recommended dose of Valezto is one film coated tablet per day.

When to take Valezto

Use as directed by your doctor or pharmacist.

Taking Valezto at the same time each day will help you remember when to take your medicine. Valezto may be taken with or without food.

How long to take Valezto

Use this medicine for the duration that your doctor recommends

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

If you forget to take Valezto

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much of this medicine may cause low blood pressure; dizziness and tachycardia (a rapid heart rate). If you have accidentally taken too many tablets of Valezto, consult your doctor immediately.

While using Valezto

Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Valezto.

Tell your doctor immediately if you become pregnant while using this medication.

Take Valezto only with a doctor's prescription.

Things you must not do

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

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Valezto to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If this medicine makes you feel dizziness and affect the ability to concentrate do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Valezto can cause side effects, although not everybody gets them.

Some side effects can be serious

Rare (affecting less than 1 in 1000 patients): Allergic reaction with symptoms such as rash, itching, swelling of face or lips or tongue, difficulty breathing, low blood pressure.

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

Other possible side effects are:

Common (affecting less than 1 in 10 patients): Flu-like symptoms; nasal congestion, sore throat and discomfort when swallowing; headache; swelling of arms, hands, legs, ankles or feet; tiredness; redness and warm feeling of the face and/or the neck.

Uncommon (affecting less than 1 in 100 patients): Dizziness; nausea and abdominal pain; dry mouth; drowsiness, tingling or numbness of the hands or feet; vertigo; fast heart beat including palpitations; dizziness on standing up; cough; diarrhea; constipation; skin rash, redness of the skin; joint swelling, back pain; pain in joints.

Rare (affecting less than 1 in 1000 patients): Anxiety; tinnitus (ringing of the ears); fainting; passing more urine than normal or feeling an increased urge to pass urine; inability to get or maintain an erection; sensation of heaviness; low blood pressure with symptoms such as dizziness, lightheadedness; excessive sweating; generalised skin rash; itching; muscle spasm.

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

Additional undesirable effects with amlodipine or valsartan alone, which can be serious are:

Amlodipine

Spontaneous bleeding or bruising (possible symptoms of thrombocytopenia), fever, sore throat or mouth ulcers due to infections (possible symptoms of leucocytopenia), sensation of numbness or tingling in fingers and toes (possible symptoms of peripheral neuropathy), irregular heart beat (possible symptoms of atrial fibrillation), slow heart beat (possible symptoms of bradycardia), sudden and oppressive chest pain (possible symptoms of myocardial infarction), rash, fever, itching (possible symptoms of vasculitis), severe upper stomach pain (possible symptoms of pancreatitis), yellow skin and eyes, nausea, loss of appetite, dark colored urine (possible symptoms of hepatitis), swelling mainly of the face and throat (possible symptoms of angioedema), rash, skin reddening, blistering of lips, eyes or mouth, skin peeling (possible symptoms of erythema multiforme), rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible symptoms of Steven-Johnson Syndrome).

Valsartan

Decreased number of white blood cells which could increase the risk of infections, blistering skin (sign of dermatitis bullous).

If you experience any of these, tell your doctor immediately. If you notice any other effects not mentioned in this leaflet, please inform 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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Valezto

Storage

Keep out of the reach and sight of children.
Store below 30°C.
Protect from light and moisture

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

Valezto 5mg/80mg: Yellow, round, biconvex, plain on both sides, film-coated tablets.

Valezto 10mg/160mg: Yellow, oblong, biconvex, plain on both sides, film-coated tablet.

Ingredients

- *Active ingredient*

The active substances of Valezto are amlodipine (5 mg or 10 mg) and valsartan (80 mg or 160 mg).

- *Inactive ingredients*

The **other ingredients** are microcrystalline cellulose, colloidal silicon dioxide, crospovidone, magnesium stearate, opadry yellow and purified water.

MAL Number

Valezto 5mg/80mg film-coated tablet:
Valezto 10mg/160mg film-coated tablet:

Manufacturer

DUOPHARMA MANUFACTURING (BANGI) SDN BHD
Lot No. 2 & 4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor, Malaysia.

Product Registration Holder

DUOPHARMA MANUFACTURING (BANGI) SDN BHD
Lot No. 2, 4, 6, 8 & 10, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor, Malaysia.

Date of Revision

27/07/2025

Serial Number

NPRA (R2) 24/103