

VALGEN-AM FILM-COATED TABLETS

Valsartan+Amlodipine Besilate (160mg+5mg, 160mg+10mg)

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What VALGEN-AM is used for

Your medicine is called **VALGEN-AM** and is available as a film-coated tablet. **VALGEN-AM** 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.

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

How VALGEN-AM 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 **VALGEN-AM** works or why this medicine has been prescribed for you, ask your doctor.

Before you use VALGEN-AM

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

- When you must not use it

- If you have ever had an unusual or allergic reaction to amlodipine besilate or valsartan or to any other ingredients of this product listed at the end of this leaflet. If you think you may be allergic, ask your doctor for advice.
- 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 *noninsulin 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 **VALGEN-AM**.

Pregnancy and lactation

Do not take **VALGEN-AM** if you are pregnant or planning to become pregnant. Use during pregnancy has been associated with serious damage to your unborn child. It is therefore important to check with your doctor immediately if you think you may have become pregnant or are planning to become pregnant.

Your doctor will discuss with you the potential risk of taking **VALGEN-AM** during pregnancy.

Tell your doctor if you are breastfeeding. Treatment with **VALGEN-AM** is not recommended during breastfeeding.

- Before you start use it

Warnings and precautions

- If you are suffering from several episodes of vomiting or diarrhoea 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 **VALGEN-**

AM and contact your doctor immediately. You should never take **VALGEN-AM** 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 **VALGEN-AM**.

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.

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 **VALGEN-AM** in children and adolescents is not recommended.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. 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, especially:

- 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:

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- 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*, *telithromycin*, *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 VALGEN-AM

It is very important that you take this medicine exactly as your doctor tells you in order to get the best results and reduce the risk of side effects.

VALGEN-AM 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 **VALGEN-AM** you should take.

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

The recommended dose of **VALGEN-AM** is one film coated tablet per day.

- When to use it

Taking **VALGEN-AM** at the same time each day will help you remember when to take your medicine.

VALGEN-AM may be taken with or without food.

- How long to use it

Continue taking **VALGEN-AM** as your doctor tells you.

If you have questions about how long to take **VALGEN-AM**, talk to your doctor or your pharmacist.

- If you forget to use it

It is advisable to take your medicine at the same time each day. If you forget to take **VALGEN-AM**, take it as soon as you remember and then take your next dose at its usual time. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for the forgotten tablet.

- If you use too much (overdose)

If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately.

Symptoms of overdose include low blood pressure; dizziness and tachycardia (a rapid heart rate). If you have accidentally taken too many tablets of **VALGEN-AM**, consult your doctor immediately.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking **VALGEN-AM**.

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

- Things you must not do

Stopping your treatment with **VALGEN-AM** may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

Do not take any new medicines without consulting your doctor.

Do not give **VALGEN-AM** to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Like many other medicines used to treat high blood pressure, **VALGEN-AM** may in rare cases cause dizziness and affect the ability to concentrate. So, before you drive a vehicle, use machinery, or carry out other activities that require concentration, make sure you know how you react to the effects of **VALGEN-AM**.

Side effects

As with all medicines, patients taking **VALGEN-AM** can experience 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.

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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
- Generalized 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, skin reddening, 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 nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of VALGEN-AM

- Storage

- Do not store above 30°C.
- Store your tablets in the original package. Protect from moisture
- Do not use **VALGEN-AM** after the expiry date which is stated on the pack.
- Keep out of the reach and sight of children.

- 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

VALGEN-AM 160MG+5MG FILM-COATED TABLETS:

Dark Yellow, oval-shaped, biconvex, film-coated tablets debossed with 'L298' on one side and plain on other side.

VALGEN-AM 160MG+10MG FILM-COATED TABLETS:

Yellow, oval-shaped, biconvex, filmcoated tablets debossed with 'L300' on one side and plain on other side.

- Ingredients

Active ingredients:

- Valsartan
- Amlodipine Besilate

Inactive ingredients:

- Cellulose microcrystalline
- Crospovidone (Type A)
- Magnesium stearate
- Silica colloidal anhydrous
- Opadry Yellow 03F520011 (**VALGEN-AM 160MG+5MG FILM-COATED TABLETS**)
- Opadry Yellow 03F520005 (**VALGEN-AM 160MG+10MG FILM-COATED TABLETS**)
- Hypromellose [E464],
- Talc [e553b]
- Iron oxide yellow [E172]
- Macrogol 6000 [E1521]
- Titanium dioxide [E171]
- Iron oxide, red (E172)

- MAL number(s):

VALGEN-AM 160MG+5MG FILM-COATED TABLETS:
MAL24056074AZ

VALGEN-AM 160MG+10MG FILM-COATED TABLETS:
MAL24056075AZ

Manufacturer

Alembic Pharmaceuticals Limited (Formulation Division), Village Panelav, P.O. Tajpura, Near Baska, Taluka Halol, Panchmahal, Gujarat – 389350 India.

Product Registration Holder

GENPHARMA SDN. BHD.
Lot 5016, Jalan Teratai,
5 ½ Mile Off Jalan Meru,
41050 Klang, Selangor, Malaysia

Date of revision

29/5/2024

Serial Number

NPRA (R2) 23/039