

VYTAN TABLET

Valsartan (80mg, 160mg)

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What Vytan Tablet is used for

Vytan is used

- to treat high bloodpressure
- to treat adult heart failure patients.
- to treat adults after a heart attack (myocardial infarction) to improve survival and reduce further heartproblems.

How Vytan Tablet works

Vytan belongs to a class of medicines known as angiotensin-II receptor antagonists, which help to control high blood pressure.

Angiotensin II is a natural substance in the body that causes blood vessels to tighten, thus causing your blood pressure to increase. Vytan works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

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

Before you use Vytan Tablet

- When you must not use it

Do not take Vytan:

- If you have ever had an unusual or allergic reaction to Vytan or to any other ingredients of this product listed at the end of this leaflet.

- If you are pregnant or are planning to get pregnant

If either of these apply to you, tell your doctor without taking Vytan.

If you think you may be allergic, ask your doctor for advice.

Take special care with Vytan:

- If you have a liverdisease
- If you have a serious kidney disease or are undergoing dialysis
- If you are already taking an ACE-inhibitor together with a beta blocker to treat your heart failure
- If you are suffering from vomiting or diarrhea or are taking high doses of a diuretic (water pill).
- 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 ever had a swelling mainly on the face and throat while taking other drugs (including an ACE-inhibitor). If you get those symptoms, stop taking Vytan and contact your doctor straight away. You should never take Vytan again.

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

Do not take this medicine after the expiry date printed on the pack or if the packaging is tom or shows signs of tampering.

If you are not sure whether you should start taking Vytan, talk to your doctor or pharmacist.

- Before you start use it

Do not take Vytan and tell your doctor if:

- You are allergic

(hypersensitive) to Vytan or any other ingredients in this medicine. The signs of an allergic reaction include a rash, itching or shortness of breath.

- You have an infection

Do not take this medicine if any of the above apply to you, talk to your doctor or pharmacist before taking Vytan.

- 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. Other medicines can affect the way Vytan works or Vytan can affect the way they work. In particular:

- medicines used to lower blood pressure, especially diuretics (water pills); 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 nonsteroidal anti-inflammatory medicines (NSAIDs) or Selective Cyclooxygenase-2 Inhibitors (Cox-2 Inhibitors). Your doctor may also check your kidney function.
- If you are below 18 years of age and you take Vytan in combination with other medicines that lower blood pressure or are used for treatment of heart failure and which work in a similar way as Vytan (e.g. so called ACE inhibitors)
- If you are below 18 years of age and you take Vytan in combination with other

medicines that inhibit the renin-angiotensin-aldosterone system (medicines that lower blood pressure), your doctor may check your kidney function and the amount of potassium in your blood at regular intervals.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Vytan Tablet.

How to use Vytan Tablet

- How much to use

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.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Vytan Tablet for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

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 think you or

anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you experience severe dizziness and/or fainting, tell your doctor as quickly as possible.

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 Vytan Tablet.

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

- Things you must not do

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

Do not take any new medicines without consulting your doctor.

Do not give Vytan Tablet 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 the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

As with all medicines, patients taking Vytan can experience side

effects, although not everybody gets them.

Some side effects could be serious (frequency unknown: frequency cannot be estimated from the available data).

You may experience symptoms of angioedema (an allergic reaction), such as:

- swollen face, tongue or throat
- difficulty in swallowing
- hives and difficulties in breathing

If you get any of these, tell your doctor straight away.

Some side effects are common (these side effects may affect between 1 and 10 in every 100 patients):

- dizziness
- low blood pressure with symptoms such as dizziness
- decreased kidney function (signs of renal impairment)

Some side effects are uncommon (these side effects may affect between 1 and 10 in every 1,000 patients):

- spinning sensation and loss of balance
- cough
- abdominal pain
- tiredness
- increase in level of potassium in the blood (which can, in severe cases, trigger muscle spasms and abnormal heart rhythm)
- loss of consciousness
- headache
- heart failure
- nausea
- diarrhea
- swelling of face or lips or tongue or throat, difficulty breathing or swallowing (symptom of angioedema)
- increase in level of serum creatinine in blood (may indicate abnormal kidney function)
- abnormal physical weakness

Also reported (frequency unknown: frequency cannot be estimated from the available data)

- decrease in level of hemoglobin and decrease in percentage of red blood cells in the blood (which can, in severe cases, lead to anaemia)
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells also called neutropenia)
- unusual bleeding or bruising (symptoms of thrombocytopenia)
- rash, itching, together with some of the following signs or symptoms: fever, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms (symptom of serum sickness)
- increase in level of potassium in the blood (which can, in severe cases, trigger muscle spasms and abnormal heart rhythm)
- purplish-red spots, fever, itching (symptoms of inflammation of blood vessels also called vasculitis)
- elevation of liver function values which can indicate liver damage including increase in serum bilirubin (which may, in severe cases, trigger yellow skin and eyes)
- swelling of face or lips or tongue or throat, difficulty breathing or swallowing (symptoms of angioedema)
- severe itching of the skin (symptom of pruritus), or inflammation of skin with presence of fluid (symptom of dermatitis bullous)
- muscle weakness
- increase in level of blood urea nitrogen or serum creatinine in blood (may indicate abnormal kidney function)

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 adult patients treated with high blood pressure than in adult patients treated for heart failure or after a recent heart attack.

If you notice any other side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell 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.moh.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of Vytan Tablet

- Storage

Keep out of the reach and sight of children. Store below 30°C.

- 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

Vytan Tablet 80mg - A light pink round shape film-coated tablet, slightly convex, scored at one side and plain on the other side.

Vytan Tablet 160mg - A light orange oval shape film-coated tablet, slightly convex, scored at one side and plain on the other side.

- Ingredients

- Active ingredient

Each tablet of Vytan Tablet 80mg and 160mg contains valsartan 80mg and 160mg respectively.

- Inactive ingredients

- a) Vytan 80mg
- microcrystalline cellulose
 - crospovidone
 - colloidal silicon dioxide
 - magnesium stearate
 - opadry pink
 - purified water

- b) Vytan 160mg
- microcrystalline cellulose
 - crospovidone
 - colloidal silicon dioxide
 - magnesium stearate
 - opadry yellow
 - purified water

- MAL number

Vytan 80mg : MAL18046155AZ
Vytan 160mg: MAL18046154AZ

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.
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