

VALSARTAN SANDOZ FILM-COATED TABLET

Valsartan (80mg, 160mg)

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What VALSARTAN SANDOZ is used for

VALSARTAN SANDOZ is used for treating high blood pressure (hypertension) in adults. It is also taken for treating a heart condition known as heart failure in adults where the heart does not pump your blood around your body as well as it should. VALSARTAN SANDOZ can also be used to treat adults after a heart attack (myocardial infarction) to improve survival and reduce further heart problems.

How VALSARTAN SANDOZ works

VALSARTAN SANDOZ is a type of medicine called an angiotensin II receptor antagonist, which by blocking the effects of the hormone angiotensin II causes the blood vessels to relax and widen. This results in a lowering of your blood pressure and makes it easier for your heart to pump blood to all parts of your body.

Before you use VALSARTAN SANDOZ

Do not take VALSARTAN SANDOZ if you are pregnant, think you might be pregnant or considering becoming pregnant. You must tell your doctor if you think you are (or might become) pregnant. VALSARTAN SANDOZ may cause serious harm or even death to your baby if used during pregnancy.

- When you must not use it
- If you are pregnant or planning to become pregnant.
- If you are allergic to any of the ingredients in VALSARTAN SANDOZ.

- If you are a Type 2 diabetic patients taking VALSARTAN SANDOZ and aliskiren concomitantly.

- Before you start to use it

Please talk to your doctor or pharmacist before taking this medicine:

- If you have any liver problems.
- If you have any kidney problems.
- 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.
- If you ever had a swelling mainly of the face and throat while taking other drugs (including an ACE-inhibitor). If you get those symptoms, stop taking VALSARTAN SANDOZ and contact your doctor straight away. You should never take VALSARTAN SANDOZ again.

- Taking other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

- If you are taking other medicines to help lower your blood pressure, particularly diuretics.
- If you are taking any other medicines including those have bought without a prescription.
- If you are taking lithium.
- If you are taking non-steroidal anti-inflammatory drugs (NSAIDs).
- If you are taking potassium supplements or salt substitutes.
- If you are taking rifampicin, ciclosporin or ritonavir.

Use in children

The safety and efficacy of VALSARTAN SANDOZ have not been established in children and adolescents (under 18 years).

How to use VALSARTAN SANDOZ

- How much to use

For high blood pressure

The usual adult dose is one 80 mg or 160 mg tablet once a day. In some cases, your doctor may prescribe a higher dose (e.g. 320 mg) or an additional medicine (e.g. a diuretic).

For heart failure

The usual starting dose is generally 40 mg twice daily. The dose is gradually increased to 80 mg twice daily and 160 mg twice daily as tolerated by the patient.

Following a heart attack

Treatment is generally started as early as 12 hours, usually at a low dose of 20 mg twice daily. Your doctor will increase this dose gradually over several weeks to a maximum of 160 mg twice daily.

- When to use it

VALSARTAN SANDOZ can be given with or without food. Always take this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure.

- How long to use it

Take VALSARTAN SANDOZ as directed by your healthcare provider. Do not stop taking your dose without talking to your healthcare provider.

- If you forget to use it

If you forget to take a dose, just carry on with the next dose as normal. Do not take an extra tablet to make up.

- If you use too much (overdose)

If you take too much, you may experience significant low blood pressure which can lead to fainting. If you take more than the recommended number of tablets, contact a doctor or pharmacist immediately (overdose).

While you are using it

- Things you must do

It is important to keep taking VALSARTAN SANDOZ every day and as your doctor has told you to. The instructions on the label should remind you of what the doctor has said. Try to take the tablets at the same time each day. It does not matter if you take VALSARTAN SANDOZ before or after your food.

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If you have the impression that the effect of VALSARTAN SANDOZ is too strong or too weak, talk to your doctor or pharmacist.

- Things you must not do

Do not stop taking your dose without talking to your healthcare provider. If you forget to take a dose, just carry on with the next dose as normal. Do not take extra tablet to make up.

- Things to be careful of

Pregnancy

You must not take VALSARTAN SANDOZ if you are pregnant, might be pregnant, or are considering becoming pregnant. You must tell your doctor if you think you are (or might become) pregnant. Your doctor will ask you to stop taking VALSARTAN SANDOZ before you become pregnant or as soon as you know you are pregnant and may recommend another medicine instead of VALSARTAN SANDOZ.

VALSARTAN SANDOZ may cause serious harm or death to your baby if used during pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. VALSARTAN SANDOZ must not be used by mothers who are breast-feeding.

Driving and using machines

The treatment of high blood pressure or heart failure may lead to dizziness or weariness in some patients. Make sure you are not affected in this way before driving or operating machines.

Side effects

Like all medicines, some people taking VALSARTAN SANDOZ may occasionally experience unwanted effects which are usually mild and do not last for long. If you suffer from any of these effects, or if you get any other unusual or unexpected symptoms, talk to your doctor or pharmacist.

Common side effects that may occur

- Dizziness
- Low blood pressure
- Worsening of your kidney function

Uncommon side effects that may occur

- Swelling of the face, lips, tongue and/or throat

- Spinning sensation
- Sudden loss of consciousness
- Cough
- Abdominal pain
- Headache
- Tiredness
- Muscle spasms, abnormal heart rhythm (signs of hyperkalemia)
- Severely decreased kidney function (signs of acute renal failure)
- Nausea
- Diarrhea
- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)

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 VALSARTAN SANDOZ

- Storage

- Do not take your tablets after the expiry date shown on the blister strip and carton.
- Keep your medicine in a safe place where children cannot reach it.
- Keep your medicine 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

- Valsartan Sandoz 80 mg: Pale red, round with beveled edges, scored on one side, with debossing “D/V” on the scored side and “NVR” on the other side.
- Valsartan Sandoz 160mg: Grey-orange, ovaloid, scored on one side; with debossing “DX/DX” on the scored side and “NVR” on the other side.

The score line on one side of Valsartan Sandoz Film-coated Tablet 80 mg or 160 mg is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

- Ingredients

Active ingredient

The active substance is *valsartan*.

Inactive ingredients

The other ingredients in the tablets are *microcrystalline cellulose, crospovidone, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide (E171), macrogol 8000, red iron oxide (E172), yellow iron oxide (E172), black iron oxide (E172: additionally for 160mg)*.

MAL Number

Valsartan Sandoz Film-coated Tablet 80 mg: MAL19056033ACZ

Valsartan Sandoz Film-coated Tablet 160 mg: MAL19056034ACZ

Manufacturer and product registration holder

Manufacturer

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80058 Torre Annunziata (NA)
Italy

Product Registration Holder

Sandoz Products Malaysia Sdn. Bhd.
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