

Vastanlupi Film Coated Tablets

valsartan (80mg and 160mg)

What is in this leaflet

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

1. What Vastanlupi is used for

Vastanlupi can be used to treat high blood pressure. High blood pressure increases the workload on 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.

Vastanlupi is used to treat adult heart failure patients. Heart failure is associated with shortness of breath, and swelling of the feet and legs due to fluid build-up. Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body.

Vastanlupi can also be used to treat adults after a heart attack (myocardial infarction) to improve survival and reduce further heart problems.

2. How Vastanlupi works

Vastanlupi belongs to a class of medicines known as angiotensin II receptor antagonist, which help to control high blood pressure. Angiotensin II is a substance in the body that causes vessels to tighten, thus causing your blood pressure to increase.

Vastanlupi works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered

3. Before you use Vastanlupi

When you must not use it

- if you are **allergic** (hypersensitive) to valsartan or any of the other ingredients of Vastanlupi.
- if you are pregnant or planning to be pregnant.

Before you use it

Follow all instructions given to you by your doctor carefully, even if they differ from the information contained in this leaflet.

Taking other medicines

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

The effect of the treatment can be influenced if Vastanlupi is taken together with certain 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 both prescription and non-prescription medicines, especially:

Other medicines that lower blood pressure, especially **water pills** (diuretics).

- **medicines that increase the amount of potassium** in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin.
- **certain type of pain killers** called non-steroidal anti-inflammatory medicines (**NSAIDs**).

4. How to use Vastanlupi

How much to use

Always take Vastanlupi exactly as your doctor has told you in order to get the best results and reduce the risk of side effects. You should check with your doctor or pharmacist if you are not sure. 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 the doctor even if you are feeling well.

For high blood pressure, the recommended dose is 80 mg or 160mg daily. In some cases your doctor may prescribe higher doses (e.g. 320 mg). He may also combine Vastanlupi with an additional medicine (e.g. a diuretic).

In heart failure the treatment starts generally with 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

Vastanlupi Film Coated Tablets

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weeks to a maximum of 160 mg twice daily.

Vastanlupi is available in only two strengths of 80mg and 160mg. They are not able to deliver all approved dose regimens of Valsartan; other approved dosage forms and strengths of Valsartan should be used in such cases.

When to use it

Take Vastanlupi at about the same time each day. You can take Vastanlupi with or without food. Swallow Vastanlupi with a glass of water.

How long to use it

Your doctor or pharmacist will advise you on how long you should continue to take your tablets. You will need to see your doctor from time to time to review your treatment and assess your symptoms.

If you forget to use it

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed.

If you use too much (overdose)

If you experience severe dizziness and/or fainting, lay down and contact your doctor immediately. If you have accidentally taken too many tablets, contact your doctor, pharmacist, or hospital.

5. While you are using Vastanlupi

Things you must do

Follow all instructions given to you by your doctor carefully, even if they differ from the

information contained in this leaflet.

Things you must not do

Before you drive a vehicle, use tools or operate machines, or carry out other activities that require concentration, make sure you know how Vastanlupi affects you.

Like many other medicines used to treat high blood pressure, Vastanlupi may in rare cases cause dizziness and affect the ability to concentrate.

Things to be careful of

Talk to your doctor or pharmacist before taking this medicine:

- if you have liver disease.
- if you have severe kidney disease or if you are undergoing dialysis.
- if you are suffering from a narrowing of the kidney artery.
- if you have recently undergone kidney transplantation (received a new kidney).
- if you are treated after a heart attack or for heart failure, your doctor may check your kidney function.
- if you have severe heart disease other than heart failure or heart attack.
- if you are taking medicines that increase the amount of potassium in your blood.

These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin. It may be necessary to check the amount of potassium in your blood at regular intervals.

- if you are below 18 years of age and you take Vastanlupi 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.

- if you suffer from aldosteronism. This is a disease in which your adrenal glands make too much of the hormone aldosterone. If this applies to you, the use of Vastanlupi is not recommended.
- if you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting, or high doses of water pills (diuretics).
- you must tell your doctor if you think you are (or might become) pregnant.

Vastanlupi is not recommended when you are pregnant or planning to pregnant. Do not take Vastanlupi while breast-feeding. Tell your doctor if you are breast-feeding.

6. Side Effects

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

Some symptoms need immediate medical attention:

You may experience symptoms of angioedema (a specific allergic reaction), such as

- swollen face, lips, tongue or throat
- difficulty in breathing or swallowing
- hives, itching

Other side effects include: Common:

Vastanlupi Film Coated Tablets

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- dizziness
- low blood pressure with or without symptoms such as dizziness and fainting when standing up
- decreased kidney function (signs of renal impairment)

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. Side effects in children and adolescents are similar to those seen in adults.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550 or visiting the website portal.bpfk.gov.my (*Consumers* → *Reporting*)

7. Storage and Disposal of Vastanlupi

- Keep this medicine out of the sight and reach of children.
- Store below 30°C. Store in the original package in order to protect from moisture.
- Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.
- Do not use this medicine if you notice that the pack is damaged or shows signs of

tampering.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

8. Product Description

What it looks like

Vastanlupi Film Coated Tablets 80 mg

Peach coloured, round, biconvex, film coated tablets, scored on one side and debossed with '80' on scored side and 'J' on the other.

Vastanlupi Film Coated Tablets 160 mg

Yellow coloured, oval shaped, biconvex, film coated tablets, scored on one side and debossed with '160' on scored side and 'J' on the other.

Ingredients

- **Active ingredient:** valsartan

- **Inactive ingredients:**

Vastanlupi Film Coated Tablets 80 mg

Cellulose Microcrystalline, Crospovidone, Silica Dental Type, Magnesium Stearate, Lactose Anhydrous, Water Purified, Opatry Pink (Hypromellose, Titanium dioxide, Macrogol, Iron oxide red, Iron oxide yellow)

Vastanlupi Film Coated Tablets 160 mg

Cellulose Microcrystalline, Crospovidone, Silica Dental Type, Magnesium Stearate, Lactose Anhydrous, Water Purified, Opadry Yellow (Hypromellose, Titanium dioxide, Macrogol, Iron oxide yellow)

MAL number

Vastanlupi Film Coated Tablets

80 mg: MALXXXXXXXXXA

Vastanlupi Film Coated Tablets

160 mg: MALXXXXXXXXXA

9. Manufacturer and Product Registration Holder

Manufacturer

Jubilant Generics Ltd.,
Village Sikandarapur Bhainswal,
Roorkee- Dehradun Highway,
Bhagwanpur, Roorkee,
District Haridwar, Uttarakhand
247 661, India

Product Registration Holder

Generic Health Sdn Bhd,
Upper Penthouse, Wisma RKT,
No. 2, Jalan Raja Abdullah,
Off Jalan Sultan Ismail, 50300
Kuala Lumpur.

10. Date of Revision

28/01/2016