Valsartan 40 mg capsules, hard
Valsartan 80 mg capsules, hard
Valsartan 160 mg capsules, hard

Package leaflet: Information for the user

Valsartan

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Warnings and precautions

• Do not take Valsartan:
  - if you are allergic to valsartan or any of the other ingredients of this medicine (listed in section 6);
  - if you have severe liver disease;
  - if you are more than 3 months pregnant.

If any of these apply to you, tell your doctor before you take Valsartan. See also information under the headings “Do not take Valsartan” and “Warnings and precautions”.

Your doctor may need to change the dose, to take other precautions, or in some cases to stop taking Valsartan capsules before you become pregnant or if you think you may be pregnant or are planning to have a baby. If your baby is newborn, or was born prematurely.

Other medicines and Valsartan

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, as it may cause serious harm to your baby if used at any time during pregnancy. Valsartan capsules is not recommended in early pregnancy.

Your doctor may need to change the dose and/or take other precautions.

If you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Valsartan” and “Warnings and precautions”).

Your doctor may choose your kidney function, blood pressure, 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.

• to treat adult patients after a recent heart attack (myocardial infarction). Valsartan should not be used for at least 12 hours and 10 days after the heart attack.

Valsartan can be used to treat symptomatic heart failure in adult patients. Valsartan is used when a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors (a medication to treat heart failure) cannot be used or may be used in addition to ACE-inhibitors when other medications to treat heart failure cannot be used.

Heart failure symptoms include shortness of breath, and swelling of the feet and legs due to fluid build-up. It is caused when the heart muscles do not pump all the blood needed throughout the body.

Valsartan capsules 80 and 160 mg can be used for three different conditions:

• to treat high blood pressure in adults and children and adolescents 6 to 18 years of age. High blood pressure increases the workload on the heart and arteries. If not treated it can damage the blood vessels in 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.

• to treat adult patients after a recent heart attack (myocardial infarction). “Recent” here means between 12 hours and 10 days. Valsartan is used when a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors (a medication to treat heart failure) cannot be used or may be used in addition to ACE-inhibitors when other medications to treat heart failure cannot be used.

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Valsartan 40 mg capsules can be used for three different conditions:

• to treat high blood pressure in children and adolescents 6 to 18 years of age. High blood pressure increases the workload on the heart and arteries. If not treated it can damage the blood vessels in 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.

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Heart failure symptoms include shortness of breath, and swelling of the feet and legs due to fluid build-up. It is caused when the heart muscles do not pump all the blood needed throughout the body.
Adult patients with high blood pressure: The recommended dose is 40 mg once daily. If your blood pressure may prescribe higher doses (e.g. 160 mg or 320 mg). He may also combine Valsartan with an additional medicine (e.g. a diuretic).

Children and adolescents (6 to 18 years of age) with high blood pressure: In children weighing 35 kg or more the recommended starting dose is 80 mg of valsartan once daily. In some patients who may require prescribed higher doses (the dose can be increased to 160 mg and to a maximum of 320 mg). Adult patients after a recent heart attack: After a heart attack the treatment with a beta blocker (which may affect your condition) for several weeks to a maximum of 160 mg twice daily. The final dose depends on what you as an individual patient can tolerate. Valsartan capsules can be given together with other treatment for heart attack, and your doctor will decide which treatment is suitable for you.

Adult patients with heart failure: Treatment starts generally with 40 mg twice daily. Your doctor will increase the dose gradually over several weeks to a maximum of 160 mg twice daily. The final dose depends on what you as an individual patient can tolerate.

Valsartan capsules can be given together with other treatment for heart failure, and your doctor will decide which treatment is suitable for you.

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

If you want more Valsartan than you should If you have to take more than one capsule, contact your doctor, pharmacist or hospital. If you forget to take Valsartan If you forget to take a dose, take as soon as you remember. 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 a forgotten dose.

If you stop taking Valsartan Stopping your treatment with Valsartan capsules may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor or pharmacist. 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.

Reporting of side effects If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Adverse drug reaction reporting (ADR) Reporting Website: www.mhra.gov.uk/yellowcard

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple Store.

3. How to store Valsartan

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 label, carton, bottle after EXP. The expiry date refers to the last day of that month. 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 protect the environment.

4. Contents of the pack and other information

What Valsartan contains The active substance is valsartan. Each hard capsule contains 40 mg/ 80 mg/ 160 mg of valsartan. The other ingredients are:

Capsule content:

- Opaque light grey cap / Flesh opaque body, size ‘1’ hard gelatin capsule, with white to off white granular powder.
- Opaque light grey cap / Flesh opaque body, size ‘2’ hard gelatin capsule, with white to off white granular powder.
- Opaque light grey cap / Flesh opaque body, size ‘3’ hard gelatin capsule, with white to off white granular powder.

Pack size:

- Opaque light grey cap / Flesh opaque body, size ‘1’ hard gelatin capsule, with white to off white granular powder.
- 28 capsules, hard
- 30 and 500 capsules, hard

Not all pack sizes may be marketed.

Marketing Authorization Holder

UK - Milpharm Limited
Aria Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

MT - Aurobindo Pharma (Malta) Limited
Villa 14, Level 2, Valletta Waterfront
Floriana FRN 1913
Malta

Manufacturer

AHP Service (Mauritius) Limited
HF26, Hal Far Industrial Estate, Hal Far Business Park, BBG 3000
Malta

Mihlpharm Limited
Aria Block, Odyssey Business Park
West End Road
Ruislip HA4 QDD
United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following name:

Malta - Valsartan 40 mg/ 80 mg/ 160 mg capsules, hard capsules

United Kingdom - Valsartan 40 mg/ 80 mg/ 160 mg capsules, hard capsules

This leaflet was last revised in 11/2017.

Malta

ADR Reporting
Website: www.mhra.gov.uk/yellowcard

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple Store.