

## Package leaflet: Information for the user

**Valsartan Aurobindo 40 mg film-coated tablets**  
**Valsartan Aurobindo 80 mg film-coated tablets**  
**Valsartan Aurobindo 160 mg film-coated tablets**  
**Valsartan Aurobindo 320 mg film-coated tablets**  
Valsartan

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet:**

1. What Valsartan Aurobindo is and what it is used for
2. What you need to know before you take Valsartan Aurobindo
3. How to take Valsartan Aurobindo
4. Possible side effects
5. How to store Valsartan Aurobindo
6. Contents of the pack and other information

### **1. What Valsartan Aurobindo is and what it is used for**

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

Valsartan Aurobindo 40 mg film-coated tablets **can be used in the following 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 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.
- **to treat adult patients after a recent heart attack** (myocardial infarction). “Recent” here means between 12 hours and 10 days.
- Valsartan Aurobindo can be used to treat symptomatic heart failure in adult patients. Valsartan Aurobindo is used when a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors (a medication to treat heart failure) cannot be used or it may be used in addition to ACE-inhibitors when other medications to treat heart failure cannot be used.

Valsartan Aurobindo 80 mg film-coated tablets **can be used for three different conditions:**

- **to treat high blood pressure in adult and 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 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.

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

Valsartan Aurobindo 160 mg film-coated tablets **can be used for three different conditions:**

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

Valsartan Aurobindo 320 mg film-coated tablets **can be used**

- **to treat high blood pressure in adults and 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 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.

## 2. What you need to know before you take Valsartan Aurobindo

### Do not take Valsartan Aurobindo:

- if you are **allergic** ( ) to valsartan or any of the other ingredients of Valsartan Aurobindo (listed in section 6).
- if you have **severe liver disease**.
- if you are **more than 3 months pregnant** (it is also better to avoid Valsartan Aurobindo in early pregnancy - see pregnancy section).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

**If any of these apply to you, do not take Valsartan Aurobindo**

### Warnings and precautions

Talk to your doctor or pharmacist before taking Valsartan Aurobindo

### Take special care with Valsartan Aurobindo:

- 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 have ever experienced swelling of the tongue and face caused by an allergic reaction called angioedema when taking another drug (including ACE inhibitors), tell your doctor. If these symptoms occur when you are taking Valsartan Aurobindo, stop taking Valsartan Aurobindo immediately and never take it again. See also section 4, “Possible side effects”.
- 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 Valsartan Aurobindo 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 Valsartan Aurobindo is not recommended.
- if you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting, or high doses of water tablets (diuretics).
- you must tell your doctor if you think you are (or might become) pregnant. Valsartan Aurobindo is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).
- if you are taking any of the following medicines used to treat high blood pressure:
  - an “ACE-inhibitor” (for example enalapril, lisinopril, ramipril, etc.), in particular if you have diabetes-related kidney problems.
  - aliskiren
- if you are being treated with an ACE-inhibitor together with certain other medicines to treat your heart failure, which are known as mineralocorticoid receptors antagonists (MRA) (for example spironolactone, eplerenone) or betablockers (for example metoprolol). Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading “Do not take Valsartan Aurobindo”

**If any of these apply to you, tell your doctor before you take Valsartan Aurobindo.**

#### **Other medicines and Valsartan Aurobindo**

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

- The effect of the treatment can be influenced if Valsartan Aurobindo 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 tablets (diuretics), ACE inhibitors (such as enalapril, lisinopril, etc.) or aliskiren.

- 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).
- some antibiotics (rifamycin group), a drug used to protect against transplant rejection (ciclosporin) or an antiretroviral drug used to treat HIV/AIDS infection (ritonavir). These drugs may increase the effect of Valsartan Aurobindo.
- **lithium**, a medicine used to treat some types of psychiatric illness.

**In addition:**

- if you are being **treated after a heart attack**, a combination with **ACE inhibitors** (a medication to treat heart attack) is not recommended.
- if you are being **treated for heart failure**, a triple combination with **ACE inhibitors and beta blockers** (medications to treat heart failure) is not recommended.

Your doctor may need to change your dose and/or to take other precautions:

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

If you are being treated with an ACE-inhibitor together with certain other medicines to treat your heart failure, which are known as mineralocorticoid receptors antagonists (MRA) (for example spironolactone, eplerenone) or betablockers (for example metoprolol).

**Taking Valsartan Aurobindo with food and drink and alcohol**

You can take Valsartan Aurobindo with or without food.

**Pregnancy and breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- **You must tell your doctor if you think that you are (or might become) pregnant.** Your doctor will normally advise you to stop taking Valsartan Aurobindo before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Valsartan Aurobindo. Valsartan Aurobindo is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if it is used after the third month of pregnancy.
- **Tell your doctor if you are breast-feeding or about to start breast-feeding.** Valsartan Aurobindo is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

**Driving and using machines**

Before you drive a vehicle, use tools or operate machines, or carry out other activities that require concentration, make sure you know how Valsartan Aurobindo affects you. Like many other medicines used to treat high blood pressure, Valsartan Aurobindo may in rare cases cause dizziness and affect the ability to concentrate.

**Valsartan Aurobindo contains**

This medicinal product contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **3. How to take Valsartan Aurobindo**

Always take this medicine 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.

**Adult patients with high blood pressure:** The usual dose is 80 mg daily. In some cases your doctor may prescribe higher doses (e.g. 160 mg or 320 mg). He may also combine Valsartan Aurobindo with an additional medicine (e.g. a diuretic).

#### **Children and adolescents (6 to 18 years of age) with high blood pressure:**

In patients who weigh less than 35 kg the usual dose is 40 mg of valsartan once daily.

In patients who weigh 35 kg or more the usual starting dose is 80 mg of valsartan once daily.

In some cases your doctor may prescribe 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 is generally started as early as after 12 hours, usually at a low dose of 20 mg twice daily. You obtain the 20 mg dose by dividing the 40 mg tablet. Your doctor will increase this 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 Aurobindo 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 Aurobindo 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 Aurobindo with or without food. Swallow Valsartan Aurobindo with a glass of water.

Take Valsartan Aurobindo at about the same time each day.

#### **If you take more Valsartan Aurobindo than you should**

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

#### **If you forget to take Valsartan Aurobindo**

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.

Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Valsartan Aurobindo**

Stopping your treatment with Valsartan Aurobindo may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

If you have further questions on the use of this product, ask your doctor or pharmacist.

#### **4. Possible side effects**

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

These side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data.

#### **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

**If you get any of these symptoms, stop taking Valsartan Aurobindo and contact your doctor straight away (see also section 2 “Take special care with Valsartan Aurobindo”).**

**Side effects include:**

#### **Common:**

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

#### **Uncommon:**

- angioedema (see section “Some symptoms need immediate medical attention”)
- sudden loss of consciousness (syncope)
- spinning sensation (vertigo)
- severely decreased kidney function (signs of acute renal failure)
- muscle spasms, abnormal heart rhythm (signs of hyperkalaemia)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- headache
- cough
- abdominal pain
- nausea
- diarrhoea
- tiredness
- weakness

#### **Not known:**

- blistering skin (sign of dermatitis bullous)

- allergic reactions with rash, itching and hives; symptoms of fever, swollen joints and joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms may occur (signs of serum sickness)
- purplish-red spots, fever, itching (signs of inflammation of blood vessels also called vasculitis)
- unusual bleeding or bruising (signs of thrombocytopenia)
- muscle pain (myalgia)
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells also called neutropenia)
- decrease of level of haemoglobin and decrease of the percentage of red blood cells in the blood (which can lead to anaemia in severe cases)
- increase of level of potassium in the blood (which can trigger muscle spasms and abnormal heart rhythm in severe cases)
- elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can trigger yellow skin and eyes in severe cases)
- increase of level of blood urea nitrogen and increase of level of serum creatinine (which can indicate abnormal kidney function)
- low level of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases)

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 via

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie)

e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Valsartan Aurobindo**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Store below 30°C.

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.

## **6. Contents of the pack and other information**

### **What Valsartan Aurobindo contains**

- The active substance is valsartan. Each film-coated tablet contains 40 mg, 80 mg, 160 mg or 320 mg valsartan.
- The other ingredients are

*Tablet core:* Cellulose microcrystalline, lactose monohydrate, silica colloidal anhydrous, crospovidone (Type B), hypromellose, sodium laurilsulfate, talc, magnesium stearate

*Tablet coating:* Hypromellose, titanium dioxide (E 171), macrogol 8000, iron oxide yellow (E 172), iron oxide red (E 172), iron oxide black (E 172) (for 320mg tablets only)

### **What Valsartan Aurobindo looks like and contents of the pack**

#### *Valsartan Aurobindo 40 mg film coated tablets*

Yellow coloured, ovaloid, beveled edge, biconvex, film coated tablets debossed with 'I' on one side and '73' on the other side with score line separating 7 and 3.

The tablet can be divided into equal doses.

#### *Valsartan Aurobindo 80 mg film coated tablets*

Pale red coloured, round, beveled edge, biconvex, film coated tablets debossed with 'I' on one side and '74' on the other side with score line separating 7 and 4.

The tablet can be divided into equal doses.

#### *Valsartan Aurobindo 160 mg film coated tablets*

Grey-orange coloured, ovaloid, beveled edge, biconvex, film coated tablets debossed with 'I' on one side and '75' on the other side with score line separating 7 and 5.

The tablet can be divided into equal doses.

#### *Valsartan Aurobindo 320 mg film coated tablets*

Dark grey-violet coloured, ovaloid, beveled edge, biconvex, film coated tablets debossed with 'I' on one side and '18' on the other side with score line separating 1 and 8.

The tablet can be divided into equal doses.

#### Clear PVC/PE/PVdC – Aluminium foil blister pack

40 mg, 80 mg & 160 mg : 7, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 & 280 tablets

320 mg: 7, 14, 20, 28, 30, 50, 56, 60, 84, 98, 100 & 280 tablets

#### HDPE container with PP closure. HDPE bottle contains silica gel as desiccant

40 mg: 30 or 1000 tablets

80 mg & 160 mg: 90, 98, 250 or 1000 tablets

320 mg: 90 or 500 tablets

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Milpharm Limited

Ares, Odyssey Business Park

West End Road

South Ruislip HA4 6QD

United Kingdom

**Manufacturer**

APL Swift Services (Malta) Limited  
HF26, Hal Far Industrial Estate, Hal Far  
Birzebbugia, BBG 3000  
Malta

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

France	Valsartan Arrow Lab 40 mg /80 mg /160 mg comprimé pelliculé sécable
Germany	Valsartan Aurobindo 40 mg /80 mg /160 mg / 320 mg Filmtabletten
Ireland	Valsartan Aurobindo 40 mg /80 mg /160 mg / 320 mg film-coated tablets
The Netherlands	Valsartan Aurobindo 40 mg /80 mg /160 mg / 320 mg filmomhulde tabletten
Poland	Valsartan Aurobindo
Portugal	Valsartan Aurobindo
Spain	Valsartan Aurobindo 40 mg /80 mg /160 mg / 320 mg comprimidos recubiertos con película

**This leaflet was last revised in 10/2015**