INSTRUCTIONS FOR USE

Valsartan Auro 40 mg, film-coated tablets
Valsartan Auro 80 mg, film-coated tablets
Valsartan Auro 160 mg, film-coated tablets
Valsartan Auro 320 mg, film-coated tablets

Valsartan

Please carefully read the instructions before you use this medication, because they contain important information for you.
- Do not throw these instructions away. You might need them later.
- Do you have any further questions? Please contact your physician or pharmacist.
- Do not give this medication to someone else, because it is prescribed to you and you alone. It can be harmful to others, even if they have the same complaints.
- Are you experiencing any of the side-effects mentioned in section 4? Or are you experiencing a side-effect that is not mentioned in the instructions for use? Please contact your physician or pharmacist.

Contents of these instructions for use
1. What is Valsartan Auro and why is this medication used?
2. When should you not take this medication, or be extra careful with it?
3. How is this medication administered?
4. Possible side-effects
5. How should this medication be stored?
6. Contents of the package and additional information

1. WHAT IS VALSARTAN AURO AND WHY IS THIS MEDICATION USED?

Valsartan Auro belongs to a family of medications known as angiotensin II receptor blockers, which help control a high blood pressure. Angiotensin II is a chemical that the body releases to cause the constriction of blood vessels, which causes the blood pressure to rise. Valsartan blocks the action of angiotensin II, resulting in the relaxation of the blood vessels. This relaxation causes the blood pressure to drop.

Valsartan Auro 40 mg, film-coated tablets can be used for three different illnesses from ages 6 to 18.
- for the treatment of high blood pressure for children and young adults aged 6 to 18.

High blood pressure increases the workload of heart and arteries. Without treatment, this could damage the arteries in the brain, heart and kidneys and lead to a stroke, heart failure or kidney failure. High blood pressure increases the chances of a heart attack. Lowering the blood pressure back to normal decreases the chance that these illnesses can develop.

- for the treatment of adult patients who recently had a heart attack (myocardial infarction). "Recent" means between 12 hours and 10 days in this regard.
- for the treatment of symptomatic heart failure in case of adult patients.

Valsartan Auro is used when

Your physician is likely to check your kidney function, blood pressure and a number of electrolytes (e.g. potassium) in your blood.

Also see the information in the section "When should you not take this medication?"

Are you using other medication?
Are you using other medication in addition to Valsartan Auro, or have you done so recently, or are going to use other medication in the future? Please tell your physician or pharmacist.

The effect of the treatment can be influenced if Valsartan Auro is administered together with certain other drugs. Your physician can adjust your dosage and/or take other measures, or in some cases urge you to stop taking one of the drugs.
This applies for both prescribed medication and medication you can buy without a prescription, in particular:
- other drugs that lower the blood pressure, in particular diuretics.
- drugs that increase the level of potassium in your blood. This includes potassium supplements, potassium-containing salt substitutes, potassium-saving drugs and heparin.
- certain kinds of pain killers called non-steroid anti-inflammatory drugs (NSAIDs).
- certain antibiotics (rifamycin family), a drug that is used against the repelling of transplants (ciclosporine), or an anti-retroviral drug that is used for HIV/AIDS infections (ritonavir). These drugs can increase the effect of Valsartan Auro.
- lithium, a drug that is used for the treatment of certain psychological diseases.

Your physician can adjust your dosage and/or undertake other measures:
- if you are taking an ACE inhibitor or aliskiren (also see the information in the sections "When should you not take this medication?" and "When should you be extra careful with this medication?")

Valsartan Auro 40 mg:
To complement this:
- if you are treated after a heart attack, the combination with ACE inhibitors when no other medication can be used for the treatment of a heart attack is not recommended.

Valsartan Auro 80 and 160 mg:
To complement this:
- if you are treated for heart failure with an ACE inhibitor together with certain other drugs; these drugs are called mineralocorticoid receptor antagonists (MRA, e.g. spironolactone, eplerenon) or beta blockers (e.g. metoprolol).
- if you are treated after a heart attack, the combination with ACE inhibitors (a drug that is used for the treatment of a heart attack) is not recommended.

Valsartan Auro 80 mg and 160 mg, film-coated tablets can be used for three different illnesses:
- for the treatment of high blood pressure in case of adults and children and young adults aged 6 to 18.

High blood pressure increases the workload of heart and arteries. Without treatment, this could damage the arteries in the brain, heart and kidneys and lead to a stroke, heart failure or kidney failure. High blood pressure increases the chances of a heart attack. Lowering the blood pressure back to normal decreases the chance that these illnesses can develop.

- for the treatment of adult patients who recently had a heart attack (myocardial infarction). "Recent" means between 12 hours and 10 days in this regard.
- for the treatment of symptomatic heart failure in case of adult patients.

Valsartan Auro is used when

What should you be aware of concerning food and drink?
You can administer Valsartan Auro with or without food.

Pregnancy and breastfeeding
Are you pregnant, do you think you are pregnant, do you want to get pregnant, or are you breastfeeding? Please contact your physician or pharmacist before you use this medicine.
- Inform your physician if you think you are pregnant (or could become pregnant). Your physician will normally advise you to stop taking Valsartan Auro before you get pregnant, or as soon as you know you are pregnant, and will advise you to take medication other than

- Are you experiencing any of the side-effects mentioned in section 4? Or are you experiencing a side-effect that is not mentioned in the instructions for use? Please contact your physician or pharmacist.

- Do you have any further questions? Please contact your physician or pharmacist.

- Do not give this medication to someone else, because it is prescribed to you and you alone. It can be harmful to others, even if they have the same complaints.

- Are you experiencing any of the side-effects mentioned in section 4? Or are you experiencing a side-effect that is not mentioned in the instructions for use? Please contact your physician or pharmacist.

- Do you have any further questions? Please contact your physician or pharmacist.

- Do not give this medication to someone else, because it is prescribed to you and you alone. It can be harmful to others, even if they have the same complaints.

- Are you experiencing any of the side-effects mentioned in section 4? Or are you experiencing a side-effect that is not mentioned in the instructions for use? Please contact your physician or pharmacist.

- Do you have any further questions? Please contact your physician or pharmacist.
ACE inhibitors (a medication for the treatment of heart failure) cannot be used, or as supplement for ACE inhibitors when no other medication can be used for the treatment of heart failure. Symptoms of heart failure include shortness of breath and swelling of the feet and legs as a result of fluid accumulation. As a result, the heart muscle is no longer able to pump hard enough to supply the entire body with the necessary blood. Valsartan Auro 320 mg film-coated tablets can be used:

- for the treatment of high blood pressure in case of adults and children and young adults aged 6 to 18. High blood pressure increases the workload of heart and arteries. Without treatment, this could damage the arteries in the brain, heart and kidneys and lead to a stroke, heart failure or kidney failure. High blood pressure increases the chances of a heart attack. Lowering the blood pressure back to normal decreases the chance that these illnesses can develop.

2. WHEN SHOULD YOU NOT USE THIS MEDICATION OR BE EXTRA CAREFUL WITH IT?

When should you not use this medication?
- If you are allergic to valsartan, peanuts, soy or one of the other substances in this medication. You can find these substances in section 6.
- If you have a severe liver condition.
- If you have been pregnant longer than 3 months (earlier on during pregnancy, it is also not recommended to use Valsartan Auro) – see the section about pregnancy.
- If you have diabetes or a kidney function disorder and you are treated with a drug that lowers the blood pressure and contains aliskiren.

If one of the above-mentioned situations applies to you, then you should not take Valsartan Auro.

When should you be extra careful with this medication?
Contact your physician, pharmacist or nurse before you use the medication
- If you have a liver condition.
- If you have a severe kidney or liver disease or if you need to be dialysed.
- If you suffer from a narrowed renal artery.
- If you recently underwent a kidney transplant (received a new kidney).
- If you are treated after a heart attack or for heart failure; your physician can check your kidney function.
- If you have a severe heart disease other than heart failure or a heart attack.
- If you ever had an allergic reaction called angioedema with swelling of the tongue and face when administering another medication (including ACE inhibitors), contact your physician. If these symptoms occur during the use of Valsartan Auro, you should stop taking Valsartan Auro immediately and never take it again. Also see section 4 “Possible side-effects”.
- If you are using drugs that increase the level of potassium in your blood. This includes potassium supplements, potassium-containing salt substitutes, potassium-saving drugs and heparin. It might be necessary to have the potassium level in your blood checked from time to time.
- If you are taking Valsartan Auro in combination with other drugs that inhibit the renin-angiotensin-aldosterone system (drugs that lower the blood pressure). Your physician can have the functioning of the kidneys and the potassium level in your blood checked from time to time.
- If you are suffering from aldosteronism. This is a disease in which your adrenal glands produce too much of the hormone aldosterone. If this is the case for you, the use of Valsartan Auro is advised against.
- If you have lost a lot of fluid (dehydration), caused by diarrhea, vomiting or the use of a high dosage of diuretics.
- If your physician or you think you are pregnant (or could become pregnant).

The use of Valsartan Auro is not recommended during the first few months of the pregnancy and should not be used if you have been pregnant longer than 3 months, because it could be severely harmful for you baby if you use it during that period (see the section on pregnancy).
- If you are using one of the following drugs for the treatment of high blood pressure:
  - an ACE inhibitor (e.g. Enalapril, Lisinopril, Ramipril), in particular if you have diabetes-related kidney problems.
  - aliskiren
  - If you are treated with an ACE inhibitor together with certain other drugs to treat heart failure, called mineralocorticoid receptor antagonists (MRA, e.g. spironolactone, eplerenon) or beta blockers (e.g. metoprolol). Valsartan Auro. The use of Valsartan Auro is advised against during the first months of the pregnancy and should not be used if you have been pregnant longer than 3 months, because use after the third month of the pregnancy can severely harm the baby.
- If you have diabetes or a kidney disease other than heart failure or a heart attack.

3. HOW IS THIS MEDICATION ADMINISTERED?
Always use this medication exactly the way your physician or pharmacist told you to. Are you having doubts about the proper use? Please contact your physician or pharmacist.
People with a high blood pressure hardly notice their condition. Most people feel very normal. Therefore, it is even more important that you keep up your appointments with your physician, even if you are feeling fine.

Valsartan Auro 40 mg
Use for children and young adults (aged 6 to 18) with high blood pressure
For patients who weigh less than 35 kg, the usual dosage is 40 mg valsartan once a day. For patients who weigh 35 kg or more, the usual initial dosage is 80 mg valsartan once a day. In some cases, your physician can prescribe a higher dosage (the dosage can be increased up to 160 mg and up to a maximum of 320 mg).

Use for adult patients after a recent heart attack: after a heart attack, the treatment is generally already started after 12 hours, usually with a low dosage of 20 mg two times a day. You can get a dosage of 20 mg by breaking a 40 mg tablet in two. Your physician will increase this dosage gradually during the course of several weeks up to a maximum of 160 mg twice a day. The final dosage depends on what you - as an individual patient - can tolerate.

Valsartan Auro can be administered together with another treatment for heart attack and your physician will decide which treatment is best for you.

Use for adult patients with heart failure: the treatment generally starts with 40 mg twice a day. Your physician will increase this dosage gradually during the course of several weeks up to a maximum of 160 mg twice a day. The final dosage depends on what you - as an individual patient - can tolerate.

Valsartan Auro can be administered together with another treatment for heart attack and your physician will decide which treatment is best for you.

Valsartan Auro 80 and 160 mg:
Use for children and young adults (aged 6 to 18) with high blood pressure
For patients who weigh less than 35 kg, the usual dosage is 40 mg valsartan once a day. For patients who weigh 35 kg or more, the usual initial dosage is 80 mg valsartan once a day. In some cases, your physician can prescribe a higher dosage (the dosage can be increased up to 160 mg and up to a maximum of 320 mg).

Use for adult patients with high blood pressure: the usual dosage is 80 mg a day. In some cases, your physician can prescribe a higher dosage (e.g. 160 mg or 320 mg). He can also combine the use of Valsartan Auro with an additional medication (e.g. a diuretic).

Use for adult patients after a recent heart attack: after a heart attack, the treatment is generally already started after 12
hours, usually with a low dosage of 20 mg twice a day. You can get a dosage of 20mg by breaking a 40 mg tablet in two. Your physician will increase this dosage gradually during the course of several weeks up to a maximum of 160 mg twice a day. The final dosage depends on what you - as an individual patient - can tolerate.

Valsartan Auro can be administered together with another treatment for heart attack and your physician will decide which treatment is best for you.

Use for adult patients after heart failure: the treatment generally starts with 40 mg twice a day. Your physician will increase this dosage gradually during the course of several weeks up to a maximum of 160 mg twice a day. The final dosage depends on what you - as an individual patient - can tolerate.

Valsartan Auro can be administered together with another treatment for heart attack and your physician will decide which treatment is best for you.

Valsartan Auro 320 mg

Use for adult patients with high blood pressure:
The usual dosage is 80 mg a day. In some cases, your physician can prescribe a higher dosage (e.g. 160 mg or 320 mg). He can also combine the use of Valsartan Auro with an additional medication (e.g. a diuretic).

Use for children and young adults (aged 6 to 18) with high blood pressure
For patients who weigh less than 35 kg, the usual dosage is 40 mg valsartan once a day. For patients who weigh 35 kg or more, the usual initial dosage is 80 mg valsartan once a day. In some cases, your physician can prescribe a higher dosage (the dosage can be increased up to 160 mg and up to a maximum of 320 mg).

You can take Valsartan Auro with or without food. Swallow the whole Valsartan Auro tablet with a glass of water. Take Valsartan Auro every day at approximately the same time.

Did you use an overdose of this medication?
If you feel dizzy or get the feeling that you are going to faint, lay down and contact your physician immediately. If you have taken too many Valsartan Auro tablets by accident, please contact your physician, pharmacist or the hospital immediately.

Did you forget to take this medication?
Never take a double dosage to compensate for a forgotten dosage.

If you forgot to take a dosage, take it as soon as you remember. However, if it is nearly time again for your next dosage, then skip the missed dosage.

If you stop taking the medication
If you terminate your treatment with Valsartan Auro, your disease could become worse. Do not stop using your medication unless your physician tells you to.

Do you have any further questions about the use of this medication?
Please contact your physician or pharmacist.

4. POSSIBLE SIDE-EFFECTS

Like every medication, this medication can also cause side-effects, although not for everyone.

The side-effects can occur with a certain frequency, defined below:
- very often: occurs for more than 1 out of 10 users
- often: occurs for 1 to 10 out of 100 users
- sometimes: occurs for 1 to 10 out of 1,000 users
- rarely: occurs for 1 to 10 out of 10,000 users
- very rarely: occurs for less than 1 out of 10,000 users
- unknown: the frequency cannot be determined based on the available data.

For some side-effects, immediate medical care is required:
Contact your physician immediately if you are experiencing the symptoms of angioedema, like:
- swelling of the face, the lips, the tongue or the throat
- problems with breathing or swallowing
- urticarial and itch

6. CONTENTS OF THE PACKAGE AND ADDITIONAL INFORMATION

Which substances does the medication contain?
- The active agent in this medication is valsartan.
- Every film-coated tablet Valsartan Auro 40 mg contains 40 mg of valsartan.
- Every film-coated tablet Valsartan Auro 80 mg contains 80 mg of valsartan.
- Every film-coated tablet Valsartan Auro 160 mg contains 160 mg of valsartan.
- Every film-coated tablet Valsartan Auro 240 mg contains 240 mg of valsartan.

Valsartan Auro 40 mg:
- The other substances in this medication are: tablet core: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, povidone K29-K32, talc, magnesium stearate, silica colloidal anhydrous. Coating: polyvinyl alcohol, macrogl 3350, talc, lecithin (contains soy oil) (E322), titanium dioxide (E171), yellow iron oxide (E172).

Valsartan Auro 80 and 160 mg:
- The other substances in this medication are: tablet core: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, povidone K29-K32, talc, magnesium stearate, silica colloidal anhydrous. Coating: polyvinyl alcohol, macrogl 3350, talc, lecithin (contains soy oil) (E322), titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172).

What does Valsartan Auro look like and how many tablets does one package contain?
Valsartan Auro 40 mg film-coated tablets: yellow, oval, biconvex, film-coated tablets, 9 x 4.5 mm, scored on one side, debossed with “V” on the other side.

Valsartan Auro 80 mg film-coated tablets: pink, round, biconvex, film-coated tablets, 8 mm diameter, scored on both sides, debossed with “V” on one side.

Valsartan Auro 160 mg film-coated tablets: yellow, oval, biconvex, film-coated tablets, 15 x 6.5 mm, scored on one side, debossed with “V” on the other side.

Valsartan Auro 240 mg film-coated tablets: brown, oval, biconvex, film-coated tablets, 19 x 8.2 mm, scored on one side, debossed with “V” on the other side.

The tablet can be divided into equal doses.

Package sizes:
Valsartan Auro 40 mg
PVC/PE/PVDC-aluminium blister pack: 7, 14, 28, 30, 56, 98 and 280 tablets

Tablet container (PE): 7, 14, 28, 30, 56, 98 and 280 tablets

Valsartan Auro 80 and 160 mg
PVC/PE/PVDC-aluminium blister pack: 7, 14, 28, 30, 56, 98 and 280 tablets

Tablet container (PE): 7, 14, 28, 30, 56, 98 and 280 tablets

Valsartan Auro 240 mg
PVC/PE/PVDC-aluminium blister pack: 7, 14, 28, 30, 56 and 98 tablets

Tablet container (PE): 100 tablets

Not all mentioned package sizes are available.

Marketing authorization holder and manufacturer:

Aurobindo Pharma B.V.
Baarnsche Dijk 1
3741 LN Baarn

For information and correspondence:

Aurobindo Pharma B.V., Baarnsche Dijk 1, 3741 LN Baarn

Manufacturer:

AstaVita Ltd., Bl.Bol16 Bulebel Industrial Estate, Zeltun ZTN 08, Malta
Balkanpharma-Dupnitsa AD, 3, Samokovsko Shosse Str., 2600 Dupnitsa, Bulgaria

Registered under:

RVG 101561 Valsartan Auro 40 mg, film-coated tablets

RVG 101566 Valsartan Auro 80 mg, film-coated tablets
low blood pressure with or without symptoms like dizziness and fainting while standing up.
- decreased kidney function (signs of a kidney dysfunction)

Sometimes (occurs for 1 out of 100 people)
- angioedema (see section “Some symptoms require immediate medical care”)
- sudden loss of consciousness (syncope)
- a dizzy feeling (vertigo)
- a severely deteriorated kidney function (signs of acute kidney failure)
- muscle spasms, abnormal heart rhythm (signs of hyperkalaemia)
- shortness of breath, problems with breathing while lying down, swelling of the feet or legs (signs that indicate heart failure)
- headache
- coughing
- stomach-ache
- nausea
- diarrhea
- tiredness
- weakness

Unknown (frequency cannot be determined based on the available data)
- allergic reactions with skin rash, itch and urticarial;
- signs of fever, swollen joints and joints pain, muscle pain, swollen lymph nodes and/or flu-like symptoms can occur (signs of serum illness)
- purplish red spots, fever, itch (symptoms of an infection of the arteries, called vasculitis)
- unusual haemorrhage or bleu spots (symptoms of thrombocytopenia)
- muscle pain (myalgia)
- fever, sore throat or mouth ulcer as a result of infections (symptoms that indicate a low white blood cell level, also called neutropenia)
- decreased of the haemoglobin value and decrease of the percentage of red blood cells in the blood (which could lead to anaemia in severe cases)
- rise of the potassium values in the blood (which could cause muscle spasms and an abnormal heart rhythm in severe cases)
- increase of the liver function values (which could indicate liver damage), including rise of bilirubin values in the blood (which could cause yellow skin and yellow sclera in severe cases)
- rise of the urea level in your blood and of the creatinine level in your serum (which could indicate an abnormal kidney function)
- low sodium level in your blood (which could cause tiredness, confusion, twitching of the muscles and/or spasms in severe cases)
- skin rash, itch

The frequency of some side-effects can be dependent on your condition. For instance, side-effects like dizziness and a deteriorated kidney function were less frequently detected in adult patients who were treated for a high blood pressure than in adult patients who were treated for heart failure or after a recent heart attack.

Side-effects for children and young adults are comparable to the side-effects that have been detected in adults.

**Reporting side-effects**

If you experience any side-effects, please contact your physician or pharmacist. This also applies if side-effects are not mentioned in these instructions for use. You can report side-effects directly via the Nederlands Bijwerkingen Centrum Lareb [The Netherlands Pharmacovigilance Centre Lareb], website: [www.lareb.nl](http://www.lareb.nl). By reporting side-effects, you can help us gain more information about the safety of the medicine.

### 5. HOW SHOULD THIS MEDICATION BE STORED?

Keep out of sight and out of reach of children.

Do not use this medication after the expiration date, which can be found on the package behind “EXP”. You will see a month and a year. The last day of the month is the final expiration date.

Do not flush this medication through the sink or toilet and do not throw it in the bin. Ask your physician what to do with medication that you no longer use. It will be disposed in a responsible way without danger to the environment.

PVC/PE/PVDC – Al. blister packs: store below 30°C.

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These instructions for use were approved most recently in March 2015.

You can find more information on this medication on the website of the College ter Beoordeling van Geneesmiddelen [Medicines Evaluation Board] ([www.cbg-med.nl](http://www.cbg-med.nl)).