

Tablet

Read all of this leaflet carefully before you start taking this medicine because it contains Important Information for you. You may need to 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 or 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.

Dosage forms and presentation

40 mg Telmisartan/ 5 mg Amlodipine, 40 mg Telmisartan/ 10 mg Amlodipine, 80 mg Telmisartan/ 5 mg Amlodipine, 80 mg Telmisartan/ 10 mg Amlodipine tablets : bottle of 30 tablets.

Indications

Arbitwin® is a combination of two active substances, Telmisartan and Amlodipine in one tablet. Both of these substances help to control high blood pressure.

Telmisartan belongs to a group of medicines which antagonise II receptor antagonists. Angiotensin-II is a substance produced in your body which angulates your blood vessels to narrow thus increasing your blood pressure. Telmisartan blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered. Amlodipine belongs to a group of substances called "calcium channel blockers". Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening. This means that both of these active substances work together to help stop your blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.

Arbitwin® is used to treat high blood pressure
• In adult patients whose blood pressure is not controlled enough with amlodipine alone.
• In adult patients who already receive telmisartan and amlodipine from separate tablets and who wish to take instead the same doses in one tablet for convenience.
High blood pressure, if not treated, can damage blood vessels in several organs, which puts patients at risk of serious events such as heart attack, heart or kidney failure, stroke, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus, it is important to regularly measure blood pressure to verify if it is within the normal range.

Warnings and precautions

Marketing Authorization Holder: Cobel Darou Co. Tehran-Iran
Manufacturing site: Dr. Abdi Pharmaceutical Tehran-Iran

Contraindications

- If you are allergic to telmisartan or amlodipine or any of the other ingredients of this medicine (see "Content of the pack and other information")
- If you are allergic to other medicines of the dihydropyridine type (one type of calcium channel blocker).
- If you are more than 3 months pregnant. (It is also better to avoid Arbitwin® in early pregnancy – see Pregnancy section.)
- If you have severe liver problems or biliary obstruction (problems with drainage of the bile from the liver and gall bladder).
- If you have narrowing of the aortic heart valve (aortic stenosis) or cardiac shock (a condition where your heart valve is unable to supply enough blood to the body).
- If you suffer from heart failure after a heart attack.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing alitiden.

If any of the above applies to you, tell your doctor or pharmacist before taking Arbitwin®.

Warnings and precautions

Talk to your doctor before taking Arbitwin® if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Kidney disease or kidney transplant.
- Narrowing of the blood vessels to one or both kidneys (renal artery stenosis).
- Liver disease.
- Heart trouble.
- Raised aldosterone levels (which lead to water and salt retention in the body along with imbalance of various blood minerals).
- Low blood pressure (hypotension), likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy ("water tablets"), low-salt diet, diarrhoea, or vomiting.
- Elevated potassium levels in your blood.
- Diabetes.
- Narrowing of the aorta (aortic stenosis).
- Heart-associated chest pain also at rest or with minimal effort (unstable angina pectoris).
- A heart attack within the last four weeks.

Talk to your doctor before taking Arbitwin®.

If you are taking any of the following medicines used to treat high blood pressure:
-an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems, alitiden.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

If you are elderly and your dose needs to be increased.
In case of surgery or anaesthesia, you should tell your doctor that you are taking Arbitwin®.

Children and adolescents

Arbitwin® is not recommended in children and adolescents up to the age of 18 years.

Other medicines and Arbitwin®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may need to change the dose of these other medicines or take other precautions. In some cases, you may have to stop taking one of the medicines. This applies especially to the medicines listed below:

- Lithium-containing medicines to treat some types of depression.
- Medicines that may increase blood potassium levels such as salt substitutes containing potassium, potassium-sparing diuretics.
- Angiotensin II receptor blockers.
- ACE-inhibitors or Aldiron (see also information under the headings "Contraindications" and "Warnings and precautions").
- NSAIDs (non-steroidal anti-inflammatory medicines, e.g. Acetylsalicylic acid or Ibuprofen), Heparin, Immunosuppressives (e.g. Cyclosporin or Tacrolimus), and the antibiotic Trimethoprim.
- Rilipamil, Erythromycin, Claritromycin (antibiotics).
- St. John's wort.
- Dantrolene (infusion for severe body temperature abnormalities).
- Medicines used to alter the way your immune system works (e.g., Stollimus, Temselimus and Everolimus).
- Medicines used for HIV/AIDS (e.g., Ritonavir) or for treatment of fungal infections (e.g., Ketoconazole).
- Diltiazem (cardiac medicine).
- Simvastatin to treat elevated levels of cholesterol.
- Digoxin.

As with other blood pressure lowering medicines, the effect of Arbitwin® may be reduced when you take NSAIDs (non-steroidal anti-inflammatory medicines, e.g. Acetylsalicylic acid or Ibuprofen) or corticosteroids.

Arbitwin® may increase the blood pressure lowering effect of other medicines used to treat high blood pressure or medicines with blood pressure lowering potential (e.g., Baclofen, Amifostine, neuroleptics or antidepressants).

Arbitwin® with food and alcohol

Low blood pressure may be aggravated by alcohol. You may notice this as dizziness when standing up. Grapefruit juice and grapefruit should not be consumed when you take Arbitwin®. This is because grapefruit and grapefruit juice may lead to increased blood levels of the active ingredient amlodipine in some patients and may increase the blood pressure lowering effect of Arbitwin®.

Pregnancy and breast-feeding

Pregnancy
You must tell your doctor if you think you might be pregnant or are planning to have a baby. Your doctor will normally advise you to stop taking Arbitwin® before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Arbitwin®. Arbitwin® 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 used after the third month of pregnancy.

Breast-feeding

Amlodipine has been shown to pass into breast milk in small amounts.
Tell your doctor if you are breast-feeding or about to start breast-feeding. Arbitwin® 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.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Some people may experience side effects such as fainting, sleepiness, dizziness or a feeling of spinning (vertigo) when they are treated for high blood pressure. If you experience these side effects, do not drive or use machines.

Dosage
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure The recommended dose is one tablet a day. Try to take the tablet at the same time each day. Remove your Arbitwin® tablet from the bottle only directly prior to taking.

You can take Arbitwin® with or without food. The tablets should be swallowed with some water or other non-alcoholic drink if your liver is not working properly, the usual dose should not exceed one 40 mg/5 mg tablet or one 40 mg/10 mg tablet per day.
If you take more Arbitwin® than you should
If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately. You might experience low blood pressure and rapid heartbeat. Slow heartbeat, dizziness, reduced kidney function including kidney failure, marked and prolonged low blood pressure including shock and death have also been reported.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24 hours after onset, include.
If you forget to take a dose, take it as soon as you remember and then carry on as before. If you do not take your tablet on one day, take your normal dose on the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking Arbitwin®
It is important that you take Arbitwin® every day until your doctor tells you otherwise. If you have the impression that the effect of Arbitwin® is too strong or too weak, talk to your doctor or pharmacist.

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

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some side effects can be serious and need immediate medical attention. You should see your doctor immediately if you experience any of the following symptoms:

Septis (often called "blood poisoning"), is a severe infection of the whole-body with high fever and the feeling of being severely ill, rapid swelling of the skin and mucosa (angioedema); these side effects are rare (may affect up to 1 in 1,000 people) but are extremely serious and patients should stop taking the medicine and see their doctor immediately. If these effects are not treated, they could be fatal. Increased incidence of sepsis has been observed with telmisartan only, however cannot be ruled out for Arbitwin®.
Common side effects (may affect up to 1 in 10 people)

Dizziness, ankle swelling (oedema).
Uncommon side effects (may affect up to 1 in 100 people)

Sleepiness, migraine, headache, stinging or numbness of the hands or feet, feeling of spinning (vertigo), slow heart rate, slight weakness (feeling of your heart beat), low blood pressure (hypotension), dizziness on standing up (orthostatic hypotension), flushing, cough, stomach ache (abdominal pain), diarrhoea, feeling sick (nausea), itching, joint pain, muscle cramps, muscle pain, inability to obtain an erection, weakness, chest pain, tiredness, swelling (oedema), increased levels of hepatic enzymes.

Rare side effects (may affect up to 1 in 10,000 people)
Urinary bladder infection, feeling of dizziness, feeling of spinning (vertigo), feeling unwell, increased levels of hepatic enzymes, increased levels of hepatic enzymes.

Very rare side effects (may affect up to 1 in 10,000 people)
Progressive scarring of lung tissue (interstitial lung disease) [mainly pneumonia of the Interstitium and pneumonia with excess eosinophils].

The following side effects have been observed with the components telmisartan or amlodipine and may occur also with Arbitwin®:

Telmisartan
In patients taking telmisartan alone the following additional side effects have been reported:
Uncommon side effects (may affect up to 1 in 100 people)
Urinary tract infections, upper respiratory tract infections (e.g., sore throat, inflamed sinuses, common cold), deficiency in red blood cells (anaemia), high potassium levels in the blood, shortness of breath, bloating, increased sweating, kidney damage including sudden inability of the kidneys to work, increased levels of creatinine.

Rare side effects (may affect up to 1 in 1,000 people)
Increase in certain white blood cells (eosinophilia), low platelet count (thrombocytopenia), allergic reaction (e.g. rash, itching, difficulty of breathing, swelling of the face or low blood pressure), high blood sugar levels (in diabetic patients), impaired vision, fast heartbeat, upset stomach, abnormal liver function, hives (urticaria), medicine rash, inflammation of the tonsils, flu-like illness (for example muscle pain, feeling generally unwell), decreased haemoglobin (a blood protein), increased levels of creatinine phosphokinase in the blood, low levels of sodium.

Amlodipine
In patients taking amlodipine alone the following additional side effects have been reported:
Common side effects (may affect up to 1 in 10 people)
Altered bowel habits, diarrhoea, constipation, visual disturbances, double vision, ankle swelling, nose.

Uncommon side effects (may affect up to 1 in 100 people)
Blood changes, impaired vision, ringing in the ears, shortness of breath, sweating/running nose, hair loss, unusual bruising and bleeding (red blood cell damage), skin discoloration, increased sweating, difficulty passing urine, increased need to pass urine especially at night, enlarging of male breasts, pain, weight increased, weight decreased.

Rare side effects (may affect up to 1 in 1,000 people)
Confusion.
Very rare side effects (may affect up to 1 in 10,000 people)
Reduced number of white blood cells (leucopenia), low platelet count (thrombocytopenia), allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure), excess sugar in blood, uncontrollable twitching or jerking movements, heart attack, irregular heartbeat, inflammation of the blood vessels, inflamed pancreas, inflammation of the stomach lining (gastritis), inflammation of the eye, yellowing of the skin (jaundice), increased levels of hepatic enzymes with jaundice, rapid swelling of skin and mucosa (angioedema), severe skin reactions, hives (urticaria), severe allergic reactions with blistering eruptions of the skin and mucous membranes (exfoliative dermatitis, Stevens-Johnson-Syndrome), increased sensitivity of the skin to sun, increased muscle tension. Not known (frequency cannot be estimated from the available data).

Severe allergic reactions with blistering eruptions of the skin and mucous membranes (toxic epidermal necrolysis).

Warnings and precautions
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:
Email: PV@cobeldarou.com
24-hour Tel: 00982188664496
00982188206129

Storage
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 carton and bottle after "EXP".
Store this medicine below 30°C and in the original package in order to protect from light and moisture. Take your Arbitwin® tablet out of the bottle only directly prior to intake.

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

Content of the pack and other information
The active substances are telmisartan and amlodipine.
Each Arbitwin® 40/5 tablet contains 40 mg of telmisartan and 5 mg of amlodipine.
Each Arbitwin® 40/10 tablet contains 40 mg of telmisartan and 10 mg of amlodipine.
Each Arbitwin® 80/5 tablet contains 80 mg of telmisartan and 5 mg of amlodipine.
Each Arbitwin® 80/10 tablet contains 80 mg of telmisartan and 10 mg of amlodipine.
Other ingredients of Arbitwin® include mannitol, corn starch, polyvidone, polysorbate 80, L-L-arginine, croscopolone, colloidal anhydrous silica, sodium hydroxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch, iron oxide and butylated hydroxytoluene.

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