AZOREN® FILM COATED TABLETS

Olmesartan Medoxomil and Amlodipine (20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg)

What is in this leaflet

What Azoren is used for

Azoren is used for the treatment of high blood pressure in patients whose blood pressure is not controlled enough with either olmesartan medoxomil or amlodipine alone.

How Azoren works

Azoren contains two substances called olmesartan medoxomil and amlodipine (as amlodipine besylate). Both of these substances help to control high blood pressure.

- Olmesartan medoxomil belongs to a group of medicines called "angiotensin-II receptor antagonists" which lower blood pressure by relaxing the blood vessels.

- 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 thereby also reducing blood pressure.

The actions of both these substances contribute to stopping the tightening of blood vessels, so that blood vessels relax and blood pressure decreases.

Before you use Azoren

- *When you must not use it*

Do not take Azoren if you:

- are allergic to olmesartan medoxomil or to amlodipine or a special group of calcium channel blockers or dihydropyridines, or any of the other ingredients of Azoren (listed in **Product Description**).
  If you think you may be allergic, talk to your doctor before taking Azoren.
- are in the second or third trimester of pregnancy (It is also better to avoid Azoren in early pregnancy - see section "Pregnancy and lactation").
- have severe liver problems.
- have bile ducts blockage bile secretion is impaired or drainage of bile from the gallbladder is blocked (e.g., by gallstones), or if you are experiencing any jaundice (yellowing of the skin and eyes).
- have very low blood pressure.
- are suffering from insufficient blood supply to your tissues (including insufficient blood supply due to heart problems) with symptoms like e.g., low blood pressure, low pulse, fast heartbeat (shock, including cardiogenic shock).
  Cardiogenic shock means shock due to severe heart troubles.
- have obstructed blood flow from your heart (e.g., because of the narrowing of the artery (aortic stenosis)).
- suffer from low heart output (resulting in shortness of breath or peripheral swellings) after a heart attack (acute myocardial infarction).
- have diabetes mellitus or renal impairment and you are treated with a blood pressure lowering medicine containing aliskiren.

Pregnancy and lactation

Do not take Azoren if you are pregnant, trying to get pregnant or think you may be pregnant.

Your doctor will normally advise you to stop taking Azoren before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Azoren.

Azoren 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.

If you become pregnant during therapy with Azoren, please inform and see your physician without delay.

Do not take Azoren if you are breast-feeding as amlodipine is excreted in human milk. It is not known if amlodipine will harm infants.

Azoren 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.

- *Before you start to use it*

Before you take these tablets, tell your doctor if you:

- Have kidney problems or a kidney transplant.
- Have liver disease.
- Have heart failure or problems with your heart valves or heart muscle.
- Have severe vomiting, diarrhea, treatment with high doses of diuretics or if you are on a low salt diet.
- Are taking medicines like ACE-inhibitors, angiotensin II receptor blockers, non-steroidal anti-inflammatory medicines or aliskiren.
- Have kidney disease caused by diabetes.
- Have increased levels of potassium in your blood due to use of potassium supplements, potassium-sparing diuretics, salt

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substitutes containing potassium, or other medicinal products that may increase potassium levels.
- Are on treatment with Lithium.
- Have problems with your adrenal glands (hormone-producing glands on top of the kidneys).
- Are pregnant or planning to become pregnant or breast-feeding.

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop, especially any of the following:

- Other blood pressure lowering medicines such as alpha blockers or diuretics. Your doctor may need to change your dose and/or to take other precautions if you are taking an ACE-inhibitor or aliskiren.
- Medicinal products affecting potassium levels such as potassium supplements, salt substitutes containing potassium, potassium sparing diuretics, ACE inhibitors or heparin (for thinning the blood and prevention of blood clots).
- Lithium used to treat mood swings and some types of depression. Using lithium at the same time as Azoren may increase the toxicity of lithium. If you have to take lithium, your doctor will measure your lithium blood levels.
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), used to relieve pain, swelling and other symptoms of inflammation, including arthritis (e.g., selective COX-2 inhibitors, acetylsalicylic acid and non-selective NSAIDs). Using NSAIDs at the same time as Azoren may increase the risk of kidney failure. The effect of Azoren can be decreased by NSAIDs.
- Certain antacids used to treat indigestion or heartburn e.g., aluminium magnesium hydroxide.
- Protease inhibitors used to treat HIV/AIDS.
- Azole antifungals used for treatment of fungal infections.
- Some antibiotics, such as erythromycin, clarithromycin, or rifampicin.
- Diltiazem and verapamil used for heart rhythm problems and high blood pressure.
- Dantrolene used to treat muscle tightness and cramping.
- Simvastatin which helps to lower cholesterol and fats in the blood.
- Tacrolimus used to treat a skin condition called eczema.
- Cyclosporine which is used to prevent organ rejection in people who have received a liver, kidney, or heart transplant.
- St. John's wort (*Hypericum perforatum*), a herbal remedy.
- Medicinal products used to lower blood pressure like ACE inhibitors angiotensin II receptor blockers or aliskiren.
- Colesevelam hydrochloride used to lower cholesterol in the blood.

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

How to use Azoren

- *How much to use*

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help. Azoren 20 mg/5 mg may be administered in patients whose blood pressure is not adequately controlled by Olmesartan Medoxomil 20 mg or Amlodipine 5 mg alone.

Azoren 40 mg/5 mg may be administered in patients whose blood pressure is not adequately controlled by Azoren 20 mg/5 mg.

Azoren 40 mg/10 mg may be administered in patients whose blood pressure is not adequately controlled by Azoren 40 mg/5 mg.

The recommended dose of Azoren is one tablet per day. The tablets can be taken with or without food. Swallow the tablet with some fluid (such as a glass of water). The tablet should not be chewed. Do not take them with grapefruit juice.

- *When to use it*

Use as directed by your doctor or pharmacist.

If possible, take your daily dose at the same time each day, for example at breakfast time.

- *How long to use it*

Continue taking Azoren for as long as your doctor recommends.

- *If you forget to use it*

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause low blood pressure, fast or slow heartbeat.

If you take more tablets than you should or if a child accidentally swallows some, go to your doctor or nearest emergency department immediately and take your medicine pack or this leaflet with you.

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Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Azoren.

Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Azoren to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Children and adolescents (under 18):
Azoren is not recommended for children and adolescents under the age of 18.

Elderly patients:
If you are over 65 years of age, your doctor will regularly check your blood pressure at any dose increase, to make sure that your blood pressure does not become too low.

Black patients:
As with other similar drugs the blood pressure lowering effect of Azoren can be somewhat less in black patients.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines until the symptoms wear off and contact your doctor immediately.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Although not many people may get them, the following side effects can be serious:
Allergic reactions, that may affect the whole body, with swelling of the face, mouth and/or larynx (voice box) together with itching and rash may occur during treatment with Azoren. **If this happens stop taking Azoren and talk to your doctor immediately.**

Azoren can cause the blood pressure to fall too low in susceptible individuals or as the result of an allergic reaction. This could cause severe light-headedness or fainting. **If this happens stop taking Azoren, talk to your doctor immediately and lie down flat.**

Frequency not known:
If you experience yellowing of the whites of the eyes, dark urine, itching of the skin, even if you started therapy with Azoren a long time ago, **contact your doctor immediately** who will evaluate your symptoms and decide on how to continue your blood pressure medication.

Other possible side effects with Azoren:

Common (may affect less than 1 in 10 people):
Dizziness; headache; swelling of ankles, feet, legs, hands, or arms; tiredness.

Uncommon (may affect less than 1 in 100 people):
Dizziness on standing up; lack of energy; tingling or numbness of hands or feet; vertigo; awareness of heart beat; fast heart beat; low blood pressure with symptoms such as dizziness, light-headedness; difficult breathing; cough; nausea; vomiting; indigestion; diarrhoea; constipation; dry mouth, upper abdominal pain; skin rash; cramps; pain in arms and legs; back pain; feeling more of an urge to pass urine; sexual inactivity; inability to get or maintain an erection; weakness.

Some changes in blood test results have also been seen and include the following:
increased as well as decreased blood potassium levels, increased blood creatinine levels, increased uric acid levels, increases in a test of liver function (gamma glutamyl transferase levels).

Rare (may affect less than 1 in 1,000 people):
Drug hypersensitivity; fainting; redness and warm feeling of the face; red itchy bumps (hives); swelling of face.

Side effects reported with use of olmesartan medoxomil or amlodipine alone, but not with Azoren or in a higher frequency:

Olmesartan medoxomil

Common (may affect less than 1 in 10 people):
Bronchitis; sore throat; runny or stuffy nose; cough; abdominal pain; stomach flu; diarrhoea; indigestion; nausea; pain in the joints or bones; back pain; blood in the urine; infection of the urinary tract; chest pain; flu-like symptoms; pain.

Changes in blood test results as increased fat levels (hypertriglyceridaemia), blood urea or uric acid increased and increase in tests of liver and muscle function.

Uncommon (may affect less than 1 in 100 people):
Reduced number of a type of blood cells, known as platelets, which can result in easily bruising or prolonged bleeding time; quick allergic reactions

that may affect the whole body and may cause breathing problems as well as a rapid fall of blood pressure that may even lead to fainting (anaphylactic reactions); angina (pain or uncomfortable feeling in the chest, known as angina pectoris); itching; eruption of the skin; allergic skin rash; rash with hives; swelling of the face; muscular pain; feeling unwell.

Rare (may affect less than 1 in 1,000 people):
Swelling of the face, mouth and/or larynx (voice box); acute kidney failure and kidney insufficiency; lethargy.

Not known (frequency cannot be estimated from the available data):
Autoimmune hepatitis - body's immune system attacks the liver causing inflammation and liver damage. You may experience yellowing of the whites of the eyes, dark urine and itching of the skin.

Amlodipine

Very common (may affect more than 1 in 10 people):
Oedema (fluid retention)

Common (may affect less than 1 in 10 people):
Abdominal pain; nausea; ankle swelling; feeling sleepy; redness and warm feeling of the face, visual disturbance (including double vision and blurred vision), awareness of heartbeat, diarrhoea, constipation, indigestion, cramps, weakness, difficult breathing.

Uncommon (may affect less than 1 in 100 people):
Trouble sleeping; sleep disturbances; mood changes including feeling anxious; depression; irritability; shiver; taste changes; fainting; ringing in the ears (tinnitus); worsening of angina pectoris (pain or uncomfortable feeling in the chest); irregular heartbeat; runny or stuffy nose; loss of hair; purplish spots or patches on the skin due to small haemorrhages (purpura); discoloration of the skin; excessive sweating; eruption of the skin; itching; red itchy bumps (hives); pain of joints or muscles; problems to pass urine; urge to pass urine at night; increased need to urinate (pass urine); breast enlargement in men; chest pain; pain, feeling unwell; increase or decrease in weight.

Rare (may affect less than 1 in 1,000 people):
Confusion

Very rare (may affect less than 1 in 10,000 people):
Reduction in the number of white cells in the blood, which could increase the risk of infections; a reduction in the number of a type of blood cells known as platelets, which can result in easily bruising or prolonged bleeding time; increase in blood glucose; increased tightness of muscles or increased resistance to passive movement (hypertonia); tingling or numbness of hands or feet; heart attack; inflammation of blood vessels; inflammation of the liver or the pancreas; inflammation of stomach lining; thickening of gums; elevated liver enzymes; yellowing of the skin and eyes; increased sensitivity of the skin to light; allergic reactions: itching, rash, swelling of the face, mouth and/or larynx (voice box) together with itching and rash, severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome, toxic epidermal necrolysis), sometimes life-threatening.

Not known (frequency cannot be estimated from the available data):
Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my
[Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Azoren

- *Storage*

  Keep out of the reach and sight of children.

  Store below 30°C.

- *Disposal*

  Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

  Azoren 20 mg/5 mg film-coated tablets are white, round with C73 on one side.

  Azoren 40 mg/5 mg film-coated tablets are cream, round with C75 on one side.

  Azoren 40 mg/10 mg film-coated tablets are brownish-red, round with C77 on one side.

- *Ingredients*
  - Active ingredients

    The active substances are olmesartan medoxomil and amlodipine (as besylate).

    Each Azoren 20 mg/5 mg film-coated tablet contains 20 mg of olmesartan medoxomil and 5 mg amlodipine (as besylate).

    Each Azoren 40 mg/5 mg film-coated tablet contains 40 mg of olmesartan medoxomil and 5 mg amlodipine (as besylate).

    Each Azoren 40 mg/10 mg film-coated tablet contains 40 mg of olmesartan medoxomil and 10 mg amlodipine (as besylate).

  - Inactive ingredients

    Tablet core: Starch, pregelatinised maize, silicified microcrystalline

cellulose (microcrystalline cellulose with colloidal silicon dioxide), croscarmellose sodium, and magnesium stearate.

Tablet coat: Polyvinyl alcohol, macrogol 3350, talc, titanium dioxide (E171), iron (III) oxide yellow (E172) (Azoren 40 mg/5 mg and 40 mg/10 mg film-coated tablets only), and iron (III) oxide red (E172) (Azoren 40 mg/10 mg film-coated tablets only).

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

- *MAL numbers*

Product Name	Registration Number
Azoren 20 mg/5 mg	MAL12055003ARZ
Azoren 40 mg/5 mg	MAL12055004ARZ
Azoren 40 mg/10 mg	MAL12055005ARZ

Manufacturer
Manufactured by:
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Product Registration Holder
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Date of Revision
01/04/2024

Serial Number
NPRA (R1/4) 01042024/063

PLD-AZOREN-0424