

AZOREN[®]

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

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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).

- 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”. It stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.

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 dihydropyridines, or any of the other ingredients of Azoren
- are in the second or third trimester of pregnancy
- have severe liver problems
- have bile ducts blockage
- have very low blood pressure.
- are suffering from insufficient blood supply to your tissues (including insufficient blood supply due to heart problems)
- if the blood flow from your heart is obstructed (e.g. because of the narrowing of the artery).

- suffer from low heart output after a heart attack.

Pregnancy and lactation

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

Do not take Azoren if you are breast-feeding. 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.
- Liver disease.
- Heart failure or problems with your heart valves or heart muscle.
- Severe vomiting, diarrhea, treatment with high doses of diuretics or if you are on a low salt diet.
- You are taking medicines like ACE-inhibitors, angiotensin II receptor blockers or aliskiren.
- Kidney disease caused by diabetes.
- Increased levels of potassium in your blood due to use of potassium supplements, potassium-sparing diuretics, salt substitutes containing potassium, or other medicinal products that may increase potassium levels.
- You are on treatment with Lithium
- Problems with your adrenal glands (hormone-producing glands on top of the kidneys).
- Pregnant or planning to become pregnant.

- Taking other medicines

Tell your doctor 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.

- 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.
- 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)
- 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.
- 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.

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.

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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. Do not take them with grapefruit juice.

- When to use it

Use as directed by your doctor or pharmacist.

- 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 heart beat.

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 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.

The most commonly reported adverse reactions during treatment with Azoren are given below:

- Swelling of the body tissues, ankles, feet or fingers
- Headache
- Dizziness
- Fatigue

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or 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

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olmesartan medoxomil and 5 mg
amlodipine (as besylate).**Date of Revision**

25/01/2019

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

NPRA (R1/1) 15012019/022

PIL-AZN-0119

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).**- MAL numbers**

| <u>Product Name</u> | <u>Registration Number</u> |
|---------------------|----------------------------|
| Azoren 20 mg/5 mg | MAL12055003ARZ |
| Azoren 40 mg/5 mg | MAL12055004ARZ |
| Azoren 40 mg/10 mg | MAL12055005ARZ |

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