

OLMEPAN FILM-COATED TABLETS

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

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What OLMEPAN is used for

OLMEPAN 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 OLMEPAN works

OLMEPAN 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 the blood vessels relax and blood pressure decreases.

Before you use OLMEPAN

- When you must not use it

Do not take Olmepan 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 OLMEPAN (listed in **Product Description**).
- are in the second or third trimester of pregnancy (It is also better to avoid

OLMEPAN 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 (eg 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 OLMEPAN if you are pregnant, trying to get pregnant or think you may be pregnant.

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

OLMEPAN 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 OLMEPAN, please inform and see your physician without delay.
Do not take OLMEPAN if you are breastfeeding as amlodipine is excreted

in human milk. It is not known if amlodipine will harm infants.

OLMEPAN is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breastfeed, 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 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 breastfeeding.

- 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

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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 OLMEPAN 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 OLMEPAN may increase the risk of kidney failure. The effect of OLMEPAN 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.
- Cyclosporin 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 OLMEPAN

- 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.

OLMEPAN 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.

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

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

The recommended dose of OLMEPAN 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 OLMEPAN 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.

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 OLMEPAN.

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.

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

- *Things to be careful of*

Children and adolescents (under 18): OLMEPAN 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 OLMEPAN 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.

Sodium content

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

Side effects

Like all medicines, OLMEPAN 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 OLMEPAN. If this happens stop taking OLMEPAN and talk to your doctor immediately.

OLMEPAN can cause the blood pressure to fall too low in susceptible individuals or as the result of an allergic reaction. This could cause severe lightheadedness or fainting. If this happens stop taking OLMEPAN, 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 OLMEPAN 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 OLMEPAN:

Common (may affect less than 1 in 10 patients):

Dizziness; headache; swelling of ankles, feet, legs, hands, or arms; tiredness.

Uncommon (may affect less than 1 in 100 patients):

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 patients):

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 OLMEPAN or in a higher frequency:

Olmesartan medoxomil

Common (may affect less than 1 in 10 patients):

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 patients):

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 patients):

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)

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Common (may affect less than 1 in 10 patients):

Abdominal pain; nausea; ankle swelling; feeling sleepy; redness and warm feeling of the face, visual disturbance (including double vision and blurred vision), awareness of heart-beat, diarrhoea, constipation, indigestion, cramps, weakness, difficult breathing.

Uncommon (may affect less than 1 in 100 patients):

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 patients):

Confusion

Very rare (may affect less than 1 in 10,000 patients):

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 OLMEPAN

- Storage

Keep out of the reach and sight of children.

Do not store above 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

OLMEPAN 20mg/5mg Film-Coated Tablets:

White round biconvex film coated tablets, engraved with 'L' on one side, plain on the other.

OLMEPAN 40mg/5mg Film-Coated Tablets:

Yellow round biconvex film coated tablets, engraved with 'I' on one side, plain on the other.

OLMEPAN 40mg/10mg Film-Coated Tablets:

Brownish-red round biconvex film coated tablets, engraved with 'H' on one side, plain on the other.

- Ingredients

Active ingredient(s)

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

OLMEPAN 20mg/5mg Film-Coated Tablets:

Each film-coated tablet contains 20 mg of Olmesartan medoxomil and 5 mg of Amlodipine (as besylate).

OLMEPAN 40mg/5mg Film-Coated Tablets:

Each film-coated tablet contains 40 mg of Olmesartan medoxomil and 5 mg of Amlodipine (as besylate).

OLMEPAN 40mg/10mg Film-Coated Tablets:

Each film-coated tablet contains 40 mg of Olmesartan medoxomil and 10 mg of Amlodipine (as besylate).

- Inactive ingredients

Tablet core

Cellulose microcrystalline
Croscarmellose sodium
Silica colloidal anhydrous
Magnesium stearate

Coating

Polyvinyl alcohol
Macrogol 3350
Talc
Titanium dioxide (E171)
Iron oxide red (E172) (for 40mg/10mg film coated tablets only)
Iron oxide yellow (E172) (for 40mg/5mg and 40mg/10mg film-coated tablets only)

- MAL numbers:

OLMEPAN 20mg/5mg Film-Coated Tablets: MAL*****
OLMEPAN 40mg/5mg Film-Coated Tablets: MAL*****
OLMEPAN 40mg/10mg Film-Coated Tablets: MAL*****

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Manufacturer

GENEPHARM S.A. 18th Km.
Marathonos Avenue, 15351 Pallini,
Greece

Product Registration Holder

Medispec (M) Sdn Bhd
B-1-07, Jalan SS 25/22,
Taman Mayang,
47301 Petaling Jaya, Selangor,
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Date of revision

5.1.2026

Serial number

NPRA (R2) 25/042