

# **OLMESARTAN/ AMLODIPINE APOTEX**

Olmesartan medoxomil and amlodipine besilate

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## **Consumer Medicine Information**

**For a copy of a large print leaflet, Ph: 1800 195 055**

## **What is in this leaflet**

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Olmesartan/Amlodipine against the benefits it is expected to have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

## What this medicine is used for

Olmesartan/Amlodipine is used to treat high blood pressure which is sometimes called hypertension.

Everyone has blood pressure. This pressure helps push blood all around your body. Your blood pressure changes at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems, including stroke, heart disease and kidney failure.

Olmesartan/Amlodipine contains olmesartan medoxomil, which belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which causes blood vessels to tighten. Olmesartan/Amlodipine blocks the action of angiotensin-II and therefore relaxes your blood vessels. This helps lower your blood pressure.

Olmesartan/Amlodipine also contains amlodipine besilate, a calcium channel blocker. This reduces the movement of calcium into the cells of the heart and blood vessels. This also helps to lower blood pressure as it relaxes the blood vessels and increases the supply of blood and oxygen to the heart.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed olmesartan/amlodipine for another reason.

This medicine is not addictive.

This medicine is only available with a doctor's prescription.

This medicine is not recommended for use in children and in the elderly.

## **Before you use this medicine**

### **When you must not take it**

**Do not take this medicine if you have an allergy to:**

- olmesartan
- amlodipine or medicines belonging to a group of chemicals called dihydropyridines used to treat blood pressure and other heart problems
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

- rash, itching or hives on the skin

**Do not take this medicine if you have any of the following medical conditions:**

- serious problems with your kidneys
- serious problems with your liver
- diabetes and are taking a medicine called aliskiren to reduce blood pressure
- recent serious heart problems
- low potassium or sodium levels in the blood

**Do not take this medicine if you are pregnant or plan to become pregnant.**

Olmesartan/Amlodipine may affect your developing baby if you take it during pregnancy.

**Do not breastfeed if you are taking this medicine.**

Olmesartan/Amlodipine may pass into breast milk and there is a possibility that your baby may be affected.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

## **Before you start to take it**

**Tell your doctor if you have allergies to any other medicines, food, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- kidney problems
- liver problems
- heart problems
- diabetes
- excessive vomiting or diarrhoea recently
- high levels of potassium in your blood
- problems with your adrenal glands (small glands above the kidneys)

**Tell your doctor if you are following a very low salt diet.**

**Tell your doctor if you are taking potassium supplements, potassium-sparing agents, potassium-containing salt substitutes or other medicines that may increase serum potassium (e.g. trimethoprim-containing products).**

**Tell your doctor if you become pregnant or plan to become pregnant or are breastfeeding.**

Your doctor can discuss with you the risks and benefits involved.

**If you have not told your doctor about any of the above, tell them before you start taking this medicine.**

## **Taking other medicines**

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you can get without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines and olmesartan/amlodipine may interfere with each other. These include:

- other medicines to treat high blood pressure
- any medicine that contains aliskiren
- medicines used to treat angina (e.g. diltiazem)
- non-steroid anti-inflammatory drugs (NSAIDs) or COX-2 inhibitors, medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis
- potassium supplements or potassium-containing salt substitutes
- other medicines that may increase serum potassium (e.g. trimethoprim-containing products)
- lithium or antidepressant medicines

- some antibiotics, such as erythromycin or rifampicin
- some antifungals, such as ketoconazole or itraconazole
- anti-proteases, medicines used to treat HIV infection such as ritonavir
- medicines which lower your immune system, such as ciclosporin and tacrolimus
- St John's Wort
- grapefruit or grapefruit juice
- any medicine that contains colesevelam

These medicines may be affected by olmesartan/amlodipine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

## **How to take this medicine**

**Follow all directions given to you by your doctor or 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.**

## **How much to take**

Take one tablet once a day.

## **How to take it**

**Swallow the tablets whole with a glass of water.**

Do not chew the tablets.

## **When to take it**

**Take your medicine at about the same time each day, with or without food.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter whether you take it with or without food.

## **How long to take it for**

Olmesartan/Amlodipine helps control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

Continue taking your medicine for as long as your doctor tells you.

## **If you forget to take it**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

**Do not take a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.**

## **If you take too much (overdose)**

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital if you think that 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.

If you take too much olmesartan/amlodipine, you may feel light-headed, dizzy or you may faint. You may also have a fast heartbeat.

## **While you are using this medicine**

### **Things you must do**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you become pregnant or start to breastfeed while taking olmesartan/amlodipine, tell your doctor immediately.**

**If you have excess vomiting and/or diarrhoea while taking olmesartan/amlodipine, tell your doctor.**

You may lose too much water and salt and your blood pressure may drop too much.

**If you feel light-headed or dizzy after taking your first dose of olmesartan/amlodipine, or when your dose is increased, tell your doctor immediately.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

Your blood pressure may drop suddenly.

**Keep all your doctor's appointments so that your progress can be checked.**

Your doctor may check your blood pressure, to make sure olmesartan/amlodipine is working.

**Your doctor may occasionally do a blood test to check your potassium levels and see how your kidneys are working.**

## **Things you must not do**

**Do not take this medicine to treat any other complaints unless your doctor tells you to.**

**Do not give this medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

## **Things to be careful of**

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure.

If this problem continues or gets worse, talk to your doctor.

**Be careful driving or operating machinery until you know how this medicine affects you.**

As with other medicines in this class, olmesartan/amlodipine may cause dizziness, light-headedness or tiredness in some people.

Make sure you know how you react to olmesartan/amlodipine before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs, do not drive.

If you drink alcohol, dizziness or light-headedness may be worse.

## **Things that would be helpful for your blood pressure**

Some self-help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

- Alcohol - your doctor may advise you to limit your alcohol intake.
- Weight - your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart must do. Some people may need a dietician's help to lose weight.
- Diet - eat a healthy diet which includes plenty of fresh vegetables, fruit, bread (preferably wholegrain), cereals and fish. Also eat less sugar and fat (especially saturated fat) which includes sausages, fatty meats, full cream dairy products, biscuits, cakes, pastries, chocolates, chips and coconut. Monounsaturated and polyunsaturated fats from

olive oil, canola oil, avocado and nuts are beneficial in small quantities.

- Salt - your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake, you should avoid using salt in cooking or at the table and avoid cooked or processed foods containing high sodium (salt) levels.
- Exercise - regular exercise, maintained over the long term, helps to reduce blood pressure and helps get the heart fitter. Regular exercise also improves your blood cholesterol levels, helps reduce your weight and stress levels, and improves your sleep, mood and ability to concentrate. However, it is important not to overdo it. Walking is good exercise but try to find a route that is reasonably flat. Before starting any exercise, ask your doctor about the best kind of programme for you.
- Smoking - your doctor may advise you to stop smoking or at least cut down. There are enormous benefits to be gained from giving up smoking. There are many professionals, organisations and strategies to help you quit. Ask your doctor or pharmacist for further information and advice.

## **Side effects**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.**

Olmesartan/Amlodipine helps most people with high blood pressure, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they

are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- feeling light-headed, dizzy or faint
- cough
- headache
- feeling sick (nausea) or vomiting
- diarrhoea
- unusual tiredness or weakness, fatigue
- 'flu-like' symptoms
- bronchitis
- sore throat and discomfort when swallowing (pharyngitis)
- back pain

- urinary tract infection
- swelling of the face, hands, feet or ankles.

The above list includes the more common side effects of your medicine.

**Tell your doctor as soon as possible if you notice any of the following:**

- skin rash or itchiness
- aching, tender or weak muscles not caused by exercise
- painful joints
- fast heart beat
- shortness of breath or tightness in the chest
- swelling of the face, hands, feet or ankles
- symptoms that may indicate high potassium levels in the blood, such as nausea, diarrhoea, muscle weakness, change in heart rhythm.

The above list includes serious side effects that may require medical attention.

**If any of the following happen, stop taking this medicine and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath or

difficulty breathing, wheezing or trouble breathing (signs of severe allergy)

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

## **Storage and Disposal**

### **Storage**

**Keep the tablets in the pack until it is time to take them.**

If you take the tablets out of the pack, they may not keep well.

**Keep this medicine in a cool dry place where the temperature stays below 25°C.**

**Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave medicines in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep your medicines where children cannot reach them.**

A locked cupboard at least one-and-a-half metres above the ground is good place to store medicines.

## **Disposal**

**If your doctor tells you to stop taking olmesartan/amlodipine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

## **Product description**

### **What it looks like**

#### **Olmesartan/Amlodipine 20/5**

White, round, biconvex, film-coated tablet debossed with “L75” on one side and plain on other side. AUST R 290089.

#### **Olmesartan/Amlodipine 20/10**

Greyish-orange, round, biconvex, film-coated tablet debossed with “L76” on one side and plain on other side. AUST R 290093.

#### **Olmesartan/Amlodipine 40/5**

Light yellow, round, biconvex, film-coated tablet debossed with “L77” on one side and plain on other side. AUST R 290094.

#### **Olmesartan/Amlodipine 40/10**

Red (brownish red), round, biconvex, film-coated tablet debossed with “L78” on one side and plain on other side. AUST R 290088.

Supplied in blister packs of 30 tablets.

## Ingredients

Olmesartan/Amlodipine 20/5 APOTEX - 20 mg olmesartan medoxomil and 5 mg amlodipine besilate.

Olmesartan/Amlodipine 20/10 APOTEX - 20 mg olmesartan medoxomil and 10 mg amlodipine as besilate.

Olmesartan/Amlodipine 40/5 APOTEX - 40 mg olmesartan medoxomil and 5 mg amlodipine besilate.

Olmesartan/Amlodipine 40/10 APOTEX - 40 mg olmesartan medoxomil and 10 mg amlodipine besilate.

Other ingredients:

- silicified microcrystalline cellulose
- colloidal anhydrous silica
- pregelatinised maize starch
- croscarmellose sodium
- magnesium stearate
- 20/5 mg: Opadry II White
- 20/10 mg: Opadry II Beige
- 40/5 mg: Opadry II Yellow

- 40/10mg: Opadry II Brown

Olmesartan/Amlodipine APOTEX does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

## **Distributor**

Apotex Pty Ltd

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Macquarie Park NSW 2113

Australia

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