

# APO-OLMESARTAN/AMLODIPINE

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

### 1. Why am I taking APO-OLMESARTAN/AMLODIPINE?

APO-OLMESARTAN/AMLODIPINE contains the active ingredients olmesartan medoxomil and amlodipine (as besilate).

APO-OLMESARTAN/AMLODIPINE is used to treat high blood pressure.

For more information, see Section [1. Why am I taking APO-OLMESARTAN/AMLODIPINE?](#) in the full CMI.

### 2. What should I know before I take APO-OLMESARTAN/AMLODIPINE?

Do not take if you have ever had an allergic reaction to APO-OLMESARTAN/AMLODIPINE or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take APO-OLMESARTAN/AMLODIPINE?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with APO-OLMESARTAN/AMLODIPINE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take APO-OLMESARTAN/AMLODIPINE?

- Follow all directions given to you by your doctor or pharmacist carefully. Your doctor will tell you which APO-OLMESARTAN/AMLODIPINE tablet you will need to take each day.
- Swallow APO-OLMESARTAN/AMLODIPINE tablet whole with a full glass of water.
- Take your APO-OLMESARTAN/AMLODIPINE tablet at the same time each day.

More instructions can be found in Section [4. How do I take APO-OLMESARTAN/AMLODIPINE?](#) in the full CMI.

### 5. What should I know while taking APO-OLMESARTAN/AMLODIPINE?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking APO-OLMESARTAN/AMLODIPINE.</li><li>• If you become pregnant while taking APO-OLMESARTAN/AMLODIPINE, tell your doctor immediately.</li><li>• Go to your doctor regularly for a check-up.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking APO-OLMESARTAN/AMLODIPINE suddenly, or lower the dosage, or take it to treat any other complaints, unless your doctor tells you to.</li><li>• Do not give APO-OLMESARTAN/AMLODIPINE to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how APO-OLMESARTAN/AMLODIPINE affects you.</li><li>• APO-OLMESARTAN/AMLODIPINE may cause dizziness, light-headedness or tiredness in some people.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li><li>• Your doctor may advise you to limit your alcohol intake.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in the carton until it is time to take them.</li><li>• Keep your tablets in a cool dry place where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while taking APO-OLMESARTAN/AMLODIPINE?](#) in the full CMI.

### 6. Are there any side effects?

There are a number of side effects associated with APO-OLMESARTAN/AMLODIPINE. It is important to be aware of them so that you can identify any symptoms if they occur. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# APO-OLMESARTAN/AMLODIPINE

Active ingredient(s): *olmesartan medoxomil and amlodipine (as besilate)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking APO-OLMESARTAN/AMLODIPINE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking APO-OLMESARTAN/AMLODIPINE.**

Where to find information in this leaflet:

- [1. Why am I taking APO-OLMESARTAN/AMLODIPINE?](#)
- [2. What should I know before I take APO-OLMESARTAN/AMLODIPINE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take APO-OLMESARTAN/AMLODIPINE?](#)
- [5. What should I know while taking APO-OLMESARTAN/AMLODIPINE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking APO-OLMESARTAN/AMLODIPINE?

APO-OLMESARTAN/AMLODIPINE contains the active ingredients olmesartan medoxomil and amlodipine (as besilate).

APO-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.

### How APO-OLMESARTAN/AMLODIPINE works

APO-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. APO-OLMESARTAN/AMLODIPINE blocks the action of angiotensin-II and therefore relaxes your blood vessels. This helps lower your blood pressure.

APO-OLMESARTAN/AMLODIPINE also contains amlodipine (as 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.

Your doctor may have prescribed APO-OLMESARTAN/AMLODIPINE for another reason. Ask your doctor if you have any questions about why APO-OLMESARTAN/AMLODIPINE has been prescribed for you.

APO-OLMESARTAN/AMLODIPINE is not addictive.

## 2. What should I know before I take APO-OLMESARTAN/AMLODIPINE?

### Warnings

Do not take APO-OLMESARTAN/AMLODIPINE if:

- you are allergic to:
  - olmesartan,
  - amlodipine (as besilate), medicines belonging to a group of chemicals called dihydropyridines used to treat blood pressure and other heart problems.
  - or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to APO-OLMESARTAN/AMLODIPINE may include skin rash, itchiness, shortness of breath, swelling of the face, lips or tongue, muscle pain or tenderness or joint pain.

- you have serious problems with your kidneys.
- you have serious problems with your liver.
- you have diabetes and are taking a medicine called aliskiren to reduce blood pressure.
- you have had recent serious heart problems.
- you have low potassium or sodium levels in the blood.
- you are pregnant or breastfeeding.
- the expiry date on the pack has passed or if the packaging is torn or shows signs of tampering.

Tell your doctor if:

- you have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- you have or have had any other medical conditions, especially the following:
  - 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).
- you are following a very low salt diet.

- you are or intend to become pregnant or plan to breastfeed.
- 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).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

**Do not take APO-OLMESARTAN/AMLODIPINE if you are pregnant or breastfeeding.**

APO-OLMESARTAN/AMLODIPINE may enter your womb or it may pass into the breast milk and there is the possibility that your baby may be affected.

If pregnancy is discovered

APO-OLMESARTAN/AMLODIPINE should be discontinued as soon as possible.

### Use in children

The safety and effectiveness of APO-OLMESARTAN/AMLODIPINE in children has not been established.

## 3. What if I am taking other medicines?

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

**Some medicines and APO-OLMESARTAN/AMLODIPINE may interfere with each other. These include:**

- Other medicines to treat high blood pressure.
- Any medicines that contain aliskiren.
- Medicines used to treat angina, such as 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 medicines that contain colessevelam.

These medicines may be affected by APO-OLMESARTAN/AMLODIPINE or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect**

**APO-OLMESARTAN/AMLODIPINE.**

## 4. How do I take APO-OLMESARTAN/AMLODIPINE?

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

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you which APO-OLMESARTAN/AMLODIPINE tablet you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

**If you do not understand the instructions on the carton, ask your doctor or pharmacist for help.**

### How much to take

- The dose of APO-OLMESARTAN/AMLODIPINE is one tablet to be taken once a day.

### When to take APO-OLMESARTAN/AMLODIPINE

- Take APO-OLMESARTAN/AMLODIPINE at about the same time each day, with or without food.

Taking your tablet at the same time each day will have the best effect. It will also help you remember when to take the tablet. It does not matter whether you take it with or without food.

### How to take APO-OLMESARTAN/AMLODIPINE

- Swallow APO-OLMESARTAN/AMLODIPINE tablet whole with a full glass of water.
- Do not chew the tablet.

### How long to take

#### APO-OLMESARTAN/AMLODIPINE

APO-OLMESARTAN/AMLODIPINE helps control your condition but does not cure it. Therefore, you must take APO-OLMESARTAN/AMLODIPINE every day. Continue taking your medicine for as long as your doctor tells you.

### If you forget to take

#### APO-OLMESARTAN/AMLODIPINE

APO-OLMESARTAN/AMLODIPINE should be taken regularly at the same time each day. 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 you missed.**

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

## If you take too much APO-OLMESARTAN/AMLODIPINE

If you think that you have taken too much APO-OLMESARTAN/AMLODIPINE, you may need urgent medical attention.

### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

### Keep telephone numbers for these places handy.

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

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

## 5. What should I know while taking APO-OLMESARTAN/AMLODIPINE?

### Things you should do

- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking APO-OLMESARTAN/AMLODIPINE.
- Have your blood pressure checked when your doctor says, to make sure APO-OLMESARTAN/AMLODIPINE is working.
- Go to your doctor regularly for a check-up. Your doctor may occasionally do a blood test to check your potassium levels and see how your kidneys are working.
- 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.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking APO-OLMESARTAN/AMLODIPINE. Your blood pressure may suddenly drop.
- If you are about to have any blood tests, tell your doctor that you are taking APO-OLMESARTAN/AMLODIPINE. APO-OLMESARTAN/AMLODIPINE may interfere with the results of some tests.

### Call your doctor straight away if you:

- **have excess vomiting and/or diarrhoea while taking APO-OLMESARTAN/AMLODIPINE.**  
You may lose too much water and salt and your blood pressure may drop too much.

- **feel light-headed or dizzy after taking your first dose of APO-OLMESARTAN/AMLODIPINE, or when your dose is increased.**
- **become pregnant while taking APO-OLMESARTAN/AMLODIPINE.**

Remind any doctor, dentist or pharmacist you visit that you are taking APO-OLMESARTAN/AMLODIPINE.

### Things you should not do

- Do not give APO-OLMESARTAN/AMLODIPINE to anyone else, even if they have the same condition as you.
- Do not take APO-OLMESARTAN/AMLODIPINE to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop taking APO-OLMESARTAN/AMLODIPINE, or lower the dosage, without checking with your doctor.

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

Some self-help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- 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 has to 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 program 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.

## Driving or using machines

**Be careful before you drive or use any machines or tools until you know how APO-OLMESARTAN/AMLODIPINE affects you.**

As with other medicines in this class, APO-OLMESARTAN/AMLODIPINE may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to APO-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.

## Drinking alcohol

**Tell your doctor if you drink alcohol.**

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

Your doctor may advise you to limit your alcohol intake.

## Looking after your medicine

- Keep your tablets in the carton until it is time to take them.  
If you take the tablets out of the carton they will not keep well.
- Keep your tablets in a cool dry place where the temperature stays below 25°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Follow the instructions on the carton on how to take care of your medicine properly.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If your doctor tells you to stop taking APO-OLMESARTAN/AMLODIPINE or it is out of date, take it to any pharmacy for safe disposal.

Do not take APO-OLMESARTAN/AMLODIPINE after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

APO-OLMESARTAN/AMLODIPINE helps most people with high blood pressure, but it may have unwanted side effects in a few people. If you are over 65 years of age you may have an increased chance of getting side effects.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>Head and nervous system-related:</b></p> <ul style="list-style-type: none"><li>• Feeling light-headed, dizzy or faint.</li><li>• Headache.</li></ul> <p><b>Gastrointestinal-related:</b></p> <ul style="list-style-type: none"><li>• Diarrhoea.</li><li>• Feeling sick (nausea) or vomiting.</li></ul> <p><b>Respiratory-related:</b></p> <ul style="list-style-type: none"><li>• Bronchitis.</li><li>• Cough.</li></ul> <p><b>General Conditions:</b></p> <ul style="list-style-type: none"><li>• Swelling of the face, hands, feet or ankles.</li><li>• Sore throat and discomfort when swallowing (pharyngitis).</li><li>• Back pain.</li><li>• Unusual tiredness or weakness, fatigue.</li><li>• 'Flu-like' symptoms.</li></ul> <p><b>Urinary system-related:</b></p> <ul style="list-style-type: none"><li>• Urinary tract infection.</li></ul>	<p>These are less serious side effects and are generally mild. Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• Skin rash or itchiness.</li><li>• Aching, tender or weak muscles not caused by exercise.</li><li>• Painful joints.</li><li>• Fast heartbeat.</li><li>• Shortness of breath or tightness in the chest.</li><li>• Swelling of the face, hands, feet or ankles.</li><li>• Yellowing of the whites of the eyes, dark urine and itching of the skin.</li><li>• Symptoms that may indicate high potassium levels in the blood, such as nausea, diarrhoea, muscle weakness, change in heart rhythm.</li></ul>	<p><b>Call your doctor as soon as possible, if you notice any of these serious side effects.</b></p> <p><b>You may need medical attention.</b></p> <p><b>These serious side effects are rare.</b></p>
<ul style="list-style-type: none"><li>• Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.</li></ul>	<p><b>Stop taking APO-OLMESARTAN/AMLODIPINE and call your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
	<b>These serious side effects are rare.</b>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

APO-OLMESARTAN/AMLODIPINE is only available with a doctor's prescription.

### What APO-OLMESARTAN/AMLODIPINE contains

<b>Active ingredient (main ingredient)</b>	<p><b>APO-OLMESARTAN/AMLODIPINE 20/5</b> 20 mg olmesartan medoxomil and 5 mg amlodipine (as besilate).</p> <p><b>APO-OLMESARTAN/AMLODIPINE 20/10</b> 20 mg olmesartan medoxomil and 10 mg amlodipine (as besilate).</p> <p><b>APO-OLMESARTAN/AMLODIPINE 40/5</b> 40 mg olmesartan medoxomil and 5 mg amlodipine (as besilate).</p> <p><b>APO-OLMESARTAN/AMLODIPINE 40/10</b> 40 mg olmesartan medoxomil and 10 mg amlodipine (as besilate).</p>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• Silicified microcrystalline cellulose.</li> <li>• Colloidal anhydrous silica.</li> <li>• Pregelatinised maize starch.</li> <li>• Croscarmellose sodium.</li> <li>• Magnesium stearate.</li> <li>• Opadry II White 85F18422 (ARTG PI No. 11376) (20/5mg).</li> <li>• Opadry II Beige 85F570003 (ARTG PI No. 111524) (20/10mg).</li> <li>• Opadry II Yellow 85F82567 (ARTG PI No. 111523) (40/5mg).</li> </ul>

	<ul style="list-style-type: none"> <li>• Opadry II Brown 85F26912 (ARTG PI No. 111506) (40/10mg).</li> </ul>
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APO-OLMESARTAN/AMLODIPINE does not contain gluten, lactose, sucrose, tartrazine, or any other azo dyes.

**Do not take this medicine if you are allergic to any of these ingredients.**

### What APO-OLMESARTAN/AMLODIPINE looks like

#### APO-OLMESARTAN/AMLODIPINE 20/5\*

White, round, biconvex, film-coated tablet debossed with "L75" on one side and plain on other side.

Blister pack of 10 or 30 tablets\*.

AUST R 290089.

#### APO-OLMESARTAN/AMLODIPINE 20/10\*

Greyish-orange, round, biconvex, film-coated tablet debossed with "L76" on one side and plain on other side.

Blister pack of 10 or 30 tablets\*.

AUST R 290093.

#### APO-OLMESARTAN/AMLODIPINE 40/5\*

Light yellow, round, biconvex, film-coated tablet debossed with "L77" on one side and plain on other side.

Blister pack of 10 or 30 tablets\*.

AUST R 290094.

#### APO-OLMESARTAN/AMLODIPINE 40/10\*

Red (brownish red), round, biconvex, film-coated tablet debossed with "L78" on one side and plain on other side.

Blister pack of 10 or 30 tablets\*.

AUST R 290088.

\*Not all strengths and pack sizes may be available.

### Who distributes

#### APO-OLMESARTAN/AMLODIPINE

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

[www.arrotex.com.au](http://www.arrotex.com.au)

This leaflet was prepared in January 2025.