

APO-Olmesartan

Consumer Medicine Information (CMI) summary

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

1. Why am I using APO-Olmesartan?

APO-Olmesartan contains the active ingredient olmesartan medoxomil. APO-Olmesartan is used to treat high blood pressure, which is sometimes called hypertension.

For more information, see Section [1. Why am I using APO-Olmesartan?](#) in the full CMI.

2. What should I know before I use APO-Olmesartan?

Do not use if you have ever had an allergic reaction to APO-Olmesartan 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 use APO-Olmesartan?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-Olmesartan 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 use APO-Olmesartan?

- The usual starting dose is 20mg once daily
- For children 6-18 years of age, (weighing more than 35 kg or more), the usual dose is 20mg once daily
- Do not give to children under one (1) year of age

More instructions can be found in Section [4. How do I use APO-Olmesartan?](#) in the full CMI.

5. What should I know while using APO-Olmesartan?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-Olmesartan.• Tell your doctor immediately if you feel light-headed or dizzy after taking your first dose of APO-Olmesartan or when your dose is increased• Make sure you drink enough water during exercise and hot weather when you are taking APO-Olmesartan
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly• Do not lower the dosage without checking with your doctor
Driving or using machines	<ul style="list-style-type: none">• APO-Olmesartan may cause dizziness, light-headedness or tiredness in some people• Be careful before you drive or operate machinery until you know how APO-Olmesartan affects you
Drinking alcohol	<ul style="list-style-type: none">• Alcohol may increase dizziness or light-headedness
Looking after your medicine	<ul style="list-style-type: none">• Keep in a cool dry place where the temperature stays below 25°C

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

6. Are there any side effects?

Call your doctor immediately or go to the nearest emergency department if you feel any chest pains or develop any anaphylactic reactions; swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

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

Active ingredient: *olmesartan medoxomil*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-Olmesartan. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using [medicine name].**

Where to find information in this leaflet:

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

1. Why am I using APO-Olmesartan?

APO-Olmesartan contains the active ingredient olmesartan medoxomil. APO-Olmesartan 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 blocks the action of angiotensin-II and therefore relaxes the blood vessels. This helps lower blood pressure.

APO-Olmesartan is used to treat high blood pressure which is also known as hypertension.

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.

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

This medicine is not addictive and is only available with a doctor's prescription.

2. What should I know before I use APO-Olmesartan?

Warnings

Do not use APO-Olmesartan if:

- 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

- it is past its expiry date oriented on the pack or if the packaging is torn or shows sign of tampering
- you are allergic to olmesartan medoxomil, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

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

Check with your doctor if you:

- have kidney problems
- have liver problems
- have heart problems
- have excessive vomiting or diarrhoea
- have high levels of potassium in your blood
- have problems with your adrenal glands (small glands above the kidneys)
- are following a very low salt diet
- are allergic to any other medicines, foods, dyes or preservatives
- are taking any medicine for any other condition

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 if you are pregnant or breastfeeding. APO-Olmesartan may enter the womb or it may pass into breast milk and there is the possibility that your baby may be affected.

If pregnancy is discovered, speak to your doctor immediately as APO-Olmesartan should be discontinued as soon as possible.

Use in Children

The safety and effectiveness of APO-Olmesartan in children aged less than 1 year 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.

The medicines listed below may be affected by APO-Olmesartan or may affect how well APO-Olmesartan works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

- medicines used to treat high blood pressure
- diuretics, also known as fluid or water tablets
- non-steroidal anti-inflammatory drugs (NSAIDs) or COX-2 inhibitors, medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- potassium supplements, potassium-sparing agents, potassium-containing salt substitutes
- medicines that may increase serum potassium (eg. trimethoprim-containing products)
- lithium, a medicine used to treat mood swings and some types of depression
- any medicines that contain aliskiren
- any medicines that contain colesevelam

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.

4. How do I use APO-Olmesartan?

How much to take / use

Adults: The usual starting dose of APO-Olmesartan is 20mg once daily. The dose may be increased to 40mg once a day if necessary.

Children 6-18 years (weighing 35 kg or more): The usual dose is one APO-Olmesartan 20mg tablet daily.

Children 6-18 years (weighing less than 35 kg): The usual dose is 10 mg once daily. APO-Olmesartan tablets cannot be divided to accommodate 10 mg dosing. Olmesartan 10 mg tablets are available from alternative brands if the 10 mg strength is required.

Children 1-5 years (weighing 5 kg or more): The dose will vary depending on your child's weight.

Children under 1 year of age: Do not give APO-Olmesartan to children under 1 of age.

Follow the instructions provided and take APO-Olmesartan until your doctor tells you to stop.

Swallow APO-Olmesartan tablets with a full glass of water. Do not chew the tablets.

When to take / use APO-Olmesartan

- Take APO-Olmesartan at the about the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.
- It does not matter if you take APO-Olmesartan before or after food.

If you forget to use APO-Olmesartan

If you miss your dose at the usual time and 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.

If you use too much APO-Olmesartan

If you think that you have used too much APO-Olmesartan, you may feel light-headed, dizzy or you may faint. You may also have a fast heartbeat.

If you think that you have taken too much APO-Olmesartan, 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.

5. What should I know while using APO-Olmesartan?

Things you should do

Make sure you drink enough water during exercise and hot weather when you are taking APO-Olmesartan, especially if you sweat a lot. If you do not drink enough water while taking APO-Olmesartan, you may feel faint, light-headed or sick. This is because your blood pressure is dropping suddenly.

If you continue to feel unwell, tell your doctor.

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. Your blood pressure may drop suddenly.

If you are about to have any blood tests, tell your doctor that you are taking APO-Olmesartan. APO-Olmesartan may interfere with the results of some tests.

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.

Have your blood pressure checked when your doctor says, to make sure APO-Olmesartan is working.

Call your doctor straight away if you:

- feel light-headed or dizzy after taking your first dose of APO-Olmesartan, or when your dose is increased
- become pregnant whilst taking APO-Olmesartan
- have excess vomiting and/or diarrhoea while taking APO-Olmesartan. You may lose too much water and salt and your blood pressure may drop too much.

Remind any doctor, dentist or pharmacist you visit that you are using APO-Olmesartan.

Things you should not do

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-Olmesartan affects you.

As with other medicines in this class, APO-Olmesartan may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to APO-Olmesartan before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

Drinking alcohol

Tell your doctor if you drink alcohol. Alcohol may increase dizziness or light-headedness.

Looking after your medicine

- Store below 25°C

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

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.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor or pharmacist tells you to stop taking APO-Olmesartan or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use APO-Olmesartan 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.

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>Body as a whole:</p> <ul style="list-style-type: none"> • Back pain • Fatigue, unusual tiredness, or weakness • Headache • Influenza-like symptoms <p>Central & peripheral nervous system:</p> <ul style="list-style-type: none"> • Dizziness <p>Gastrointestinal system:</p> <ul style="list-style-type: none"> • Diarrhoea • Nausea or vomiting • Abdominal pain <p>Respiratory system:</p> <ul style="list-style-type: none"> • Bronchitis • Coughing • Inflammation of the back of the throat • Rhinitis <p>Urinary system:</p> <ul style="list-style-type: none"> • Urinary tract infection 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>
<p>Body as a whole:</p> <ul style="list-style-type: none"> • Swelling of legs or hands <p>Skin and subcutaneous tissue:</p> <ul style="list-style-type: none"> • Skin rash or itchiness <p>Musculoskeletal system:</p> <ul style="list-style-type: none"> • Joint pain • Aching, tender or weak muscles not caused by exercise <p>Cardiovascular system:</p> <ul style="list-style-type: none"> • Fast heartbeat • Shortness of breath or tightness in the chest 	

Serious side effects

Serious side effects	What to do
Body as a whole: <ul style="list-style-type: none">Chest pain Immune system: <ul style="list-style-type: none">Anaphylactic reactions such as swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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. 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

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

What APO-Olmesartan contains

Active ingredient (main ingredient)	olmesartan medoxomil
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">lactose monohydratemicrocrystalline celluloselow-substituted hydroxypropylcellulosehydroxypropylcellulosemagnesium stearateOpadry Yellow 03F82788
Potential allergens	sugars (as lactose)

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

What APO-Olmesartan looks like

20 mg tablets (AUST R 221052):

Yellow film coated, round, biconvex tablets debossed with '323' on one side and 'L' on other side.

40 mg tablets (AUST R 221603):

Yellow film coated, oval shape, biconvex tablets debossed with 'L324' on one side and plain on other side. AUST R 221063.

Available in blister packs of 30 tablets.

Who distributes APO-Olmesartan

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street
Cremorne, VIC, 3121
www.arrotex.com.au

This leaflet was prepared in December 2023.