

Olmesartan/Amlodipine Sandoz®

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 Olmesartan/Amlodipine Sandoz?

Olmesartan/Amlodipine Sandoz contains the active ingredient olmesartan medoxomil and amlodipine besilate. Olmesartan/Amlodipine Sandoz is used to treat high blood pressure which is sometimes called hypertension. For more information, see Section [1. Why am I using Olmesartan/Amlodipine Sandoz?](#) in the full CMI.

2. What should I know before I use Olmesartan/Amlodipine Sandoz?

Do not use if you have ever had an allergic reaction to olmesartan medoxomil or amlodipine besilate 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 Olmesartan/Amlodipine Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Olmesartan/Amlodipine Sandoz 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 Olmesartan/ Amlodipine Sandoz?

- The recommended dose is one tablet to be taken once a day.
- Swallow the tablet whole with a glass of water and take Olmesartan/ Amlodipine Sandoz at about the same time each day. More instructions can be found in Section [4. How do I use Olmesartan/Amlodipine Sandoz?](#) in the full CMI.

5. What should I know while using Olmesartan/ Amlodipine Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Olmesartan/Amlodipine Sandoz.• Tell your doctor immediately if you feel light-headed or dizzy after taking your first dose of Olmesartan/Amlodipine Sandoz, or when your dose is increased.• Tell your doctor immediately if you become pregnant while taking Olmesartan/ Amlodipine Sandoz.• Go to your doctor regularly for a check up.
Things you should not do	<ul style="list-style-type: none">• Do not take Olmesartan/ Amlodipine Sandoz to treat any other complaints unless your doctor or pharmacist tells you to.• Do not stop taking Olmesartan/ Amlodipine Sandoz, or lower the dosage, without checking with your doctor
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Olmesartan/ Amlodipine Sandoz affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep Olmesartan/ Amlodipine Sandoz tablets in a cool dry place where the temperature stays below 25°C. Store in original container. Protect from moisture.• Keep away from children.

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

6. Are there any side effects?

Common side effects: light-headedness, dizziness, faintness, cough, headache, nausea, vomiting, diarrhoea, unusual tiredness or weakness, fatigue, 'flu-like' symptoms.

Serious side effects: skin rash or itchiness, aching or tender muscles not caused by exercise, painful joints, fast heart beat or change in heart rhythm.

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.

Olmesartan/Amlodipine Sandoz®

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using Olmesartan/ Amlodipine Sandoz. **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 Olmesartan/ Amlodipine Sandoz.**

Where to find information in this leaflet:

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

1. Why am I using Olmesartan/ Amlodipine Sandoz?

Olmesartan/ Amlodipine Sandoz contains the active ingredient olmesartan medoxomil and amlodipine besilate.

Olmesartan/ Amlodipine Sandoz 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 Sandoz blocks the action of angiotensin-II and therefore relaxes your blood vessels. This helps lower your blood pressure.

Olmesartan/ Amlodipine Sandoz 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.

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

2. What should I know before I use Olmesartan/ Amlodipine Sandoz?

Warnings

Do not use Olmesartan/ Amlodipine Sandoz if:

- you are allergic to contains olmesartan medoxomil or amlodipine besilate, or any of the ingredients listed at

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

- 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 printed on the pack or if the packaging is torn or shows signs of tampering

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have kidney problems
- have liver problems
- have heart problems
- have diabetes
- have excessive vomiting or diarrhoea recently
- 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 or intend to become pregnant or plan to breastfeed
- 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?](#)

Use in children

- The safety and effectiveness of Olmesartan/ Amlodipine Sandoz in children have not been established.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Olmesartan/ Amlodipine Sandoz may enter the womb or it may pass into the breast milk and there is the possibility that your baby may be affected.

If pregnancy is discovered, Olmesartan/ Amlodipine Sandoz should be discontinued as soon as possible.

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 may interfere Olmesartan/ Amlodipine Sandoz and affect how it works.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Olmesartan/ Amlodipine Sandoz.

4. How do I use Olmesartan/ Amlodipine Sandoz?

How much to take

- The recommended dose is one tablet to be taken once a day.
- Follow the instructions provided and use Olmesartan/ Amlodipine Sandoz until your doctor tells you to stop.
- Follow all directions given to you by your doctor or pharmacist carefully. If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

When to take Olmesartan/ Amlodipine Sandoz

- Olmesartan/ Amlodipine Sandoz should be used at about the same time each day.

How to take Olmesartan/ Amlodipine Sandoz

- Swallow Olmesartan/ Amlodipine Sandoz whole with a full glass of water.
- Olmesartan/ Amlodipine Sandoz can be taken with or without food.

How long to take

Olmesartan/ Amlodipine Sandoz helps control your condition, but does not cure it. Therefore, you must take Olmesartan/ Amlodipine Sandoz every day. Continue taking your medicine for as long as your doctor tells you.

If you forget to use Olmesartan/ Amlodipine Sandoz

Olmesartan/ Amlodipine Sandoz should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember and then go back to taking your medicine as you would normally.

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

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

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

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

If you use too much Olmesartan/ Amlodipine Sandoz

If you think that you have used too much Olmesartan/ Amlodipine Sandoz, you may need urgent medical attention. You may feel light-headed, dizzy or may faint. You may also have a fast heart beat.

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 Olmesartan/ Amlodipine Sandoz?

Things you should do

- Tell your doctor if you have excess vomiting and/ or diarrhoea while taking Olmesartan/ Amlodipine Sandoz. You may lose too much water and salt and your blood pressure may drop too much.
- Tell your doctor immediately if you feel light-headed or dizzy after taking your first dose of Olmesartan/ Amlodipine Sandoz, or when your dose is increased. If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

- Tell your doctor or dentist that you are taking Olmesartan/ Amlodipine Sandoz if you plan to have surgery that needs a general anaesthetic. Your blood pressure may drop suddenly.
- Tell your doctor immediately if you become pregnant while taking Olmesartan/ Amlodipine Sandoz.
- Tell your doctor that you are taking Olmesartan/ Amlodipine Sandoz if you are about to have any blood tests. Olmesartan/ Amlodipine Sandoz may interfere with the results of some tests.
- Have your blood pressure checked when your doctor says, to make sure taking Olmesartan/ Amlodipine Sandoz 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.

Remind any doctor, dentist or pharmacist you visit that you are using Olmesartan/ Amlodipine Sandoz.

Things you should not do

- Do not give Olmesartan/ Amlodipine Sandoz to anyone else, even if they have the same condition as you.
- Do not take Olmesartan/ Amlodipine Sandoz to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop taking Olmesartan/ Amlodipine Sandoz, 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 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Olmesartan/ Amlodipine Sandoz affects you.

Olmesartan/ Amlodipine Sandoz may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to Olmesartan/ Amlodipine Sandoz 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may worsen dizziness or light-headedness.

Looking after your medicine

- Store your tablets where the temperature stays below 25°C. Store in original container. Protect from moisture.

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

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 this medicine 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
<ul style="list-style-type: none">feeling light-headed, dizzy or faintcoughheadachefeeling sick (nausea) or vomitingdiarrhoeaunusual tiredness or weakness, fatigue'flu-like' symptomsbronchitissore throat and discomfort when swallowing (pharyngitis)back painurinary tract infectionswelling of the face, hands, feet or ankles	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>They are generally mild and do not cause patients to stop taking Olmesartan/ Amlodipine Sandoz.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">skin rash or itchinessaching, tender or weak muscles not caused by exercisepainful jointsfast heart beatshortness of breath or tightness in the chestswelling of the face, hands, feet or anklesyellowing of the whites of the eyes, dark urine and itching of the skinsymptoms that may indicate high potassium levels in the blood, such as nausea, diarrhoea, muscle weakness, change in heart rhythm.swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing	<p>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.</p>

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 Olmesartan/ Amlodipine Sandoz contains

Active ingredient (main ingredient)	Each tablet contains 20 mg olmesartan medoxomil and 5 mg amlodipine (as besilate) or 40 mg olmesartan medoxomil and 5 mg amlodipine (as besilate) or 40 mg olmesartan medoxomil and 10 mg amlodipine (as besilate)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">lactose monohydratecroscarmellose sodiumpregelatinised maize starchsilicified microcrystalline cellulosemagnesium stearateOpadry II white(85F18422) – 20/5mgOpadry II yellow (85F220144)- 40/5mgOpadry II orange(85F230047) – 40/10mg
Potential allergens	<ul style="list-style-type: none">lactose

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

What Olmesartan/ Amlodipine Sandoz looks like

Olmesartan/ Amlodipine Sandoz 20/5 – white to off white round film-coated tablet debossed with "20 5" on one side, approximately 7.1 mm in diameter (Aust R 366894).

Olmesartan/ Amlodipine Sandoz 40/5 – yellow round film-coated tablet debossed with "40 5" on one side; approximately 9.1 mm in diameter (Aust R 366893).

Olmesartan/ Amlodipine Sandoz 40/10 – pink round film-coated tablet debossed with "40 10" on one side; approximately 9.1 mm in diameter (Aust R 366892).

Who distributes Olmesartan/ Amlodipine Sandoz

Sandoz Pty Ltd

ABN 60 075 449 553

54 Waterloo Road

Macquarie Park, NSW 2113

Tel: 1800 726 369

This leaflet was revised in December 2022.