

# Olmesartan/HCT 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/HCT Sandoz?

Olmesartan/HCT Sandoz contains the active ingredient olmesartan medoxomil and hydrochlorothiazide. Olmesartan/HCT Sandoz is used to treat high blood pressure.

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

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

Do not use if you have ever had an allergic reaction to olmesartan, sulfonamide derived medicines (e.g. thiazide diuretics), 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/HCT Sandoz?](#) in the full CMI.

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

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

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

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

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

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Olmesartan/HCT Sandoz.</li><li>• If you become pregnant while taking Olmesartan/HCT Sandoz, 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 using this medicine suddenly, or lower the dosage, or take it to treat any other complaints, unless your doctor tells you to.</li><li>• Do not give Olmesartan/HCT Sandoz 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 Olmesartan/HCT Sandoz affects you.</li><li>• Olmesartan/HCT Sandoz 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 box until it is time to take them. 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 using Olmesartan/HCT Sandoz?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects may include dizziness, feeling light-headed, cough, headache, feeling nauseous or vomiting, diarrhoea, tiredness, 'flu-like' symptoms, sore throat and difficulty swallowing, back pain, swelling of the face or body, blurred vision, jaundice, skin rash, depression and urinary infection. Serious side effects may include swelling of the face, lips tongue or throat which causes difficulty swallowing or breathing, muscle or joint pain, fast heartbeat and chest pain.

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/HCT Sandoz®

Active ingredient(s): *olmesartan medoxomil, hydrochlorothiazide*

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

## 1. Why am I using Olmesartan/HCT Sandoz?

**Olmesartan/HCT Sandoz contains the active ingredients olmesartan medoxomil and hydrochlorothiazide.**

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

Olmesartan/HCT Sandoz also contains hydrochlorothiazide, a diuretic which reduces the amount of fluid in the body. This also helps to lower blood pressure.

**Olmesartan/HCT Sandoz 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/HCT Sandoz is not addictive.

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

### Warnings

**Do not use Olmesartan/HCT Sandoz if:**

- **you have an allergy to olmesartan, sulfonamide derived medicines (e.g. thiazide diuretics), or any of the ingredients listed at the end of this leaflet.** Symptoms of an allergic reaction to Olmesartan/HCT Sandoz 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 low potassium or sodium levels in the blood
- you have high calcium or uric acid levels in the blood.
- you are pregnant or breast-feeding
- you have diabetes and are taking a medicine called aliskiren to reduce blood pressure
- 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
  - gout
  - Systemic Lupus Erythematosus, a disease affecting the skin, joints and kidneys
  - 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)
- you have skin cancer or if you develop a new skin lesion during treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Discuss with your doctor how to protect your skin from sun exposure, and avoid artificial tanning.

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 Olmesartan/HCT Sandoz if you are pregnant or breastfeeding.**

Olmesartan/HCT Sandoz 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 Olmesartan/HCT Sandoz should be discontinued as soon as possible.

## Use in children

The safety and effectiveness of olmesartan medoxomil and hydrochlorothiazide 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 Olmesartan/HCT Sandoz may interfere with each other. These include:

- other medicines to treat high blood pressure
- other diuretics, also known as fluid or water tablets
- 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
- insulin and tablets used to treat diabetes
- antacids, medicines used to treat heartburn and indigestion
- medicines which lower your immune system, such as corticosteroids and cytotoxic medicines used to treat cancer (including radiation therapy)
- alcohol
- laxatives, medicines used to treat constipation
- medicines used to relieve pain
- medicines used to treat epilepsy
- antiarrhythmics which treat irregular heartbeats
- muscle relaxants
- colestyramine and colestipol, used to treat high cholesterol
- any medicines that contain colesevelam
- any medicines that contain aliskiren.

These medicines may be affected by Olmesartan/HCT Sandoz, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

**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/HCT Sandoz.**

## 4. How do I use Olmesartan/HCT Sandoz?

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

### How much to take

- The dose of Olmesartan/HCT Sandoz is one tablet to be taken once a day.

### How to take Olmesartan/HCT Sandoz

- Swallow Olmesartan/HCT Sandoz whole with a full glass of water.
- Do not chew the tablets.

### When to take Olmesartan/HCT Sandoz

- **Take Olmesartan/HCT Sandoz at about the same time each day.**  
Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.
- It does not matter whether you take it with or without food.

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

### If you forget to use Olmesartan/HCT Sandoz

Olmesartan/HCT 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 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.**

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

### If you use too much Olmesartan/HCT Sandoz

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

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

### 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 Olmesartan/HCT Sandoz.
- Have your blood pressure checked when your doctor says, to make sure Olmesartan/HCT 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.
- 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 Olmesartan/HCT Sandoz. Your blood pressure may drop suddenly.
- If you are about to have any blood tests, tell your doctor that you are taking Olmesartan/HCT Sandoz. Olmesartan/HCT Sandoz may interfere with the results of some tests.
- Tell your doctor if photosensitivity reaction occurs during your treatment.
- Make sure you drink enough water during exercise and hot weather when you take Olmesartan/HCT Sandoz, especially if you sweat a lot. If you do not drink enough water while taking Olmesartan/HCT Sandoz, 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.

### Call your doctor straight away if you:

- **have excess vomiting and/or diarrhoea while taking Olmesartan/HCT Sandoz.**  
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 Olmesartan/HCT Sandoz, or when your dose is increased.**
- **become pregnant while taking Olmesartan/HCT Sandoz.**
- **experience acute onset of decreased visual acuity or ocular pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Olmesartan/HCT Sandoz. This can lead to permanent vision loss, if not treated.**
- **you experience any fever, severe shortness of breath, breathing faster than normal, difficulty**

**breathing, slightly blue fingertips and lips after taking Olmesartan/HCT Sandoz. Stop the medication and seek medical attention immediately.**

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

### Things you should not do

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

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

Make sure you know how you react to Olmesartan/HCT 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

### 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 box until it is time to take them.**

If you take the tablets out of the box they will not keep well.

- **Keep your tablets in a cool dry place where the temperature stays 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.**

### 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.

<p><b>Gastrointestinal-related:</b></p> <ul style="list-style-type: none"> <li>• diarrhoea or constipation</li> <li>• feeling sick (nausea) or vomiting</li> <li>• stomach pain</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> <li>• an uncomfortable feeling in the stomach</li> </ul> <p><b>Mood-related:</b></p> <ul style="list-style-type: none"> <li>• sleep disturbance</li> <li>• depression</li> </ul> <p><b>Respiratory-related:</b></p> <ul style="list-style-type: none"> <li>• bronchitis</li> <li>• cough</li> <li>• runny or blocked nose, or sneezing</li> </ul> <p><b>Skin-related:</b></p> <ul style="list-style-type: none"> <li>• skin rashes or eczema</li> </ul> <p><b>Liver and biliary-related:</b></p> <ul style="list-style-type: none"> <li>• jaundice</li> </ul> <p><b>Urinary system-related:</b></p> <ul style="list-style-type: none"> <li>• urinary tract infection</li> </ul>	<p><b>serious side effects and they worry you.</b></p>
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## 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.

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>Eye-related:</b></p> <ul style="list-style-type: none"> <li>• blurred vision</li> </ul>	<p><b>These are common side effects and are generally mild. Speak to your doctor if you have any of these less</b></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> <li>• Hydrochlorothiazide increases sensitivity of the skin to the sun and may increase the risk of</li> </ul>	<p><b>Call your doctor as soon as possible, if you notice any of these serious side effects. You may need medical attention.</b></p> <p><b>Serious side effects are rare.</b></p>

<p>some types of skin and lip cancer (non-melanoma skin cancer).</p> <ul style="list-style-type: none"> <li>Hydrochlorothiazide may cause a decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma</li> </ul>	
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	<p>magnesium stearate hypromellose Opadry Yellow 03F82788</p>
<b>Potential allergens</b>	Lactose monohydrate

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

### What Olmesartan/HCT Sandoz looks like

Olmesartan/HCT Sandoz tablets come in four strengths and each has a different appearance:

- Olmesartan/HCT Sandoz 20/12.5 mg is a yellow film coated, round, biconvex tablet debossed with '346' on one side and 'L' on other side (Aust R 221119).
- Olmesartan/HCT Sandoz 20/25 mg is a yellow film coated, oval shape, biconvex tablet debossed with 'L400' on one side and plain on other side (Aust R 221117).
- Olmesartan/HCT Sandoz 40/12.5 mg is a yellow film coated, oval shape, biconvex tablet debossed with 'L347' on one side and plain on other side (Aust R 221124).
- Olmesartan/HCT Sandoz 40/25 mg is a yellow film coated, oval shape, biconvex tablet debossed with 'L348' on one side and plain on other side (Aust R 221130).

The product is presented in blister packs of 30 film-coated tablets.

*Not all strengths are available in Australia.*

### Who distributes Olmesartan/HCT Sandoz

Sandoz Pty Ltd  
100 Pacific Highway  
North Sydney, NSW 2060  
Australia  
Tel 1800 726 369

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### Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> <li>Hydrochlorothiazide may cause fever, severe shortness of breath, breathing faster than normal, difficulty breathing, slightly blue fingertips and lips.</li> <li>swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing</li> <li>chest pain</li> </ul>	<p><b>Stop taking Olmesartan/HCT Sandoz 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>

**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

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

### What Olmesartan/HCT Sandoz contains

<b>Active ingredient (main ingredient)</b>	<p>olmesartan medoxomil hydrochlorothiazide</p>
<b>Other ingredients (inactive ingredients)</b>	<p>lactose monohydrate microcrystalline cellulose hypromellose</p>