

OLSETAN

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 OLSETAN?

OLSETAN contains the active ingredient Olmesartan medoxomil. OLSETAN is used to treat high blood pressure.

For more information, see Section [1. Why am I taking OLSETAN?](#) in the full CMI.

2. What should I know before I take OLSETAN?

Do not take if you have ever had an allergic reaction to OLSETAN 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 OLSETAN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with OLSETAN 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 OLSETAN?

- For adult patients & children aged 6 – 18 years and weighing 35 Kg or more; the usual dose is 20 mg once daily.
- **Do not give OLSETAN to children under 1 year of age.**

More instructions can be found in Section [4. How do I take OLSETAN?](#) in the full CMI.

5. What should I know while using OLSETAN?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking OLSETAN. • Tell your doctor immediately, if you feel light-headed or dizzy after taking your first dose of OLSETAN, or when your dose is increased, • Make sure you drink enough water during exercise and hot weather when you are taking OLSETAN.
Things you should not do	• Do not stop taking this medicine suddenly. • Do not lower the dosage, without checking with your doctor.
Driving or using machines	• OLSETAN may cause dizziness, light-headedness or tiredness in some people. • Be careful before you drive or use any machines or tools until you know how OLSETAN affects you.
Drinking alcohol	• Alcohol may increase dizziness or light-headedness.
Looking after your medicine	• Keep in a cool dry place where the temperature stays below 25 °C.

For more information, see Section [5. What should I know while taking OLSETAN?](#) 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.

OLSETAN

Active ingredient: [Olmesartan medoxomil]

Consumer Medicine Information (CMI)

This leaflet provides important information about taking OLSETAN. **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 OLSETAN.**

Where to find information in this leaflet:

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

1. Why am I using OLSETAN?

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

OLSETAN 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 OLSETAN for another reason. Ask your doctor if you have any questions about why OLSETAN has been prescribed for you.

2. What should I know before I take OLSETAN?

Warnings

Do not take OLSETAN 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
- 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 take this medicine.

Symptoms of an allergic reaction to OLSETAN may include skin rash, itchiness, shortness of breath, swelling of the

face, lips or tongue, muscle pain or tenderness or joint pain.

Do not take OLSETAN after 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 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 or intend to become pregnant or plan to breastfeed
- are following a very low salt diet
- are allergic to any other medicines, foods, dyes, or preservatives
- take 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 OLSETAN if you are pregnant or breastfeeding.

OLSETAN 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 OLSETAN should be discontinued as soon as possible.

Use in Children

- The safety and effectiveness of OLSETAN 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 OLSETAN, or may affect how well OLSETAN 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 (e.g., 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 OLSETAN.

4. How do I take OLSETAN?

How much to take

- For most adult patients, the usual starting dose of OLSETAN is 20 mg once a day. The dose may need to be increased to OLSETAN 40 mg once a day if necessary.
- **Do not give OLSETAN to children under 1 year of age.**
- For children 6-18 years (weighing 35 kg or more): One OLSETAN 20 mg tablet once daily.
- For children 6-18 years (weighing less than 35 kg) & for children 1 – 5 years (weighing 5 g or more) OLSETAN is given as a suspension. The suspension is to be prepared by a compounding pharmacist using the 20 mg tablet.
- Follow the instructions provided and take OLSETAN until your doctor tells you to stop.
- Swallow OLSETAN tablets while with a full glass of water. Do not chew the tablets.

When to take OLSETAN

- OLSETAN should be taken at about the same time each day, with or without food.
- OLSETAN helps control your condition, but does not cure it. Therefore, you must take OLSETAN every day. Continue taking your medicine for as long as your doctor tells you to.

If you forget to take OLSETAN

OLSETAN should be used regularly at the same time each day.

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 take too much OLSETAN

If you take too much OLSETAN, 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 OLSETAN, 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 OLSETAN?

Things you should do

Make sure you drink enough water during exercise and hot weather when you are taking OLSETAN, especially if you sweat a lot. If you do not drink enough water while taking OLSETAN, 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 anesthetic, tell your doctor or dentist that you are taking OLSETAN. Your blood pressure may drop suddenly.

If you are about to have any blood tests, tell your doctor that you are taking OLSETAN. OLSETAN 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 OLSETAN is working.

Call your doctor straight away if you:

- feel light-headed or dizzy after taking your first dose of OLSETAN, or when your dose is increased, **tell your doctor immediately.**
- If you become pregnant while taking OLSETAN, **tell your doctor immediately.**
- If you have excess vomiting and/or diarrhoea while taking OLSETAN, tell your doctor. 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 OLSETAN.

Things you should not do

- Do not stop taking OLSETAN suddenly or lower the dosage, without checking with your doctor.
- Do not take OLSETAN to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not give OLSETAN 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 OLSETAN affects you.

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

Alcohol may increase dizziness or light-headedness.

Looking after your medicine

- Keep the tablets in the box until it is time to take them. If the tablets are taken out of the box they will not keep well.
- Keep the 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.

The suspension should be refrigerated at 2-8°C (DO NOT FREEZE) and can be stored for up to 4 weeks. Shake well before use.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor or pharmacist tells you to stop taking OLSETAN 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 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.

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

Less serious side effects

Less serious side effects	What to do
Body as a whole: • Back pain • Fatigue, unusual tiredness, or weakness • Headache • Influenza-like symptoms Central & peripheral nervous system: • Dizziness Gastrointestinal system: • Diarrhoea • Nausea or vomiting • Abdominal pain Respiratory system: • Bronchitis • Coughing • Pharyngitis (inflammation of the back of the throat) • Rhinitis Urinary system: • Urinary tract infection	Speak to your doctor if you have any of these less serious side effects and they worry you.
Body as a whole: • Oedema peripheral (Swelling of legs or hands) Skin and subcutaneous tissue: • skin rash or itchiness Musculoskeletal system: • Arthralgia (Joint pain) • Myalgia (muscles pain); aching, tender or weak muscles not caused by exercise Cardiovascular system: • Fast heart beat • shortness of breath or tightness in the chest	Tell your doctor as soon as possible if you notice any of the following

Serious side effects

Serious side effects	What to do
Body as a whole: • Chest pain Immune system: • Anaphylactic reactions; 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

Serious side effects	What to do
	these serious side effects.

These are very serious side effects. You may need urgent medical attention or hospitalization. These side effects are very rare.

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.

OLSETAN are film coated tablets, registered in the following strengths; 10 mg, 20 mg, and 40 mg.

What OLSETAN contains

Active ingredient (main ingredient)	Olmesartan medoxomil
Other ingredients (inactive ingredients)	• Hyprollose • Hypromellose • Microcrystalline cellulose • Lactose monohydrate • Magnesium stearate • Purified Talc • Titanium dioxide
Potential allergens	Lactose monohydrate

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

What OLSETAN looks like

OLSETAN 10 mg is white to off-white, round, biconvex, film coated tablets, debossed with "IO2" on one side and plain on other side (Aust R 358593).

OLSETAN 20 mg is white to off-white, round, biconvex, film coated tablets, debossed with "IO3" on one side and plain on other side (Aust R 358608).

OLSETAN 40 mg is white to off-white, oval, biconvex, film coated tablets, debossed with "IO4" on one side and plain on other side (Aust R 358594).

Who sponsors OLSETAN

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne VIC 3000

Who distributes OLSETAN

Viatrix Pty Ltd
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatrix.com.au
Phone: 1800 274 276

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