

APO-OLMESARTAN HCTZ

Olmесartan medoxomil and hydrochlorothiazide

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about olmesartan/HCTZ. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking olmesartan/HCTZ against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What this medicine is used for

APO-Olmesartan HCTZ contains two medicines, olmesartan and hydrochlorothiazide (HCTZ). These two medicines work together to treat high blood pressure (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 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 high blood pressure. The only way of knowing that you have high blood pressure is to have your blood

pressure checked on a regular basis. Untreated high blood pressure can lead to serious health problems, including stroke, heart disease and kidney failure.

How it works

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

HCTZ is a diuretic which reduces the amount of fluid in the body. This also helps to lower blood pressure.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is not addictive.

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

The safety and effectiveness of olmesartan/HCTZ in children has not been established.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- olmesartan

- sulfonamide derived medicines (e.g. thiazide diuretics)
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- skin rash, itchiness
- shortness of breath
- swelling of the face, lips or tongue
- muscle pain or tenderness, joint pain.

Do not take this medicine if you have or have had the following medical conditions:

- kidney or liver problems
- low potassium or sodium levels in the blood
- high calcium or uric acid levels in the blood.
- diabetes and are taking a medicine called aliskiren to reduce blood pressure.

Do not take this medicine if you are pregnant or breastfeeding.

This medicine 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, this medicine should be discontinued as soon as possible.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, or any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney, liver or heart problems
- diabetes
- recent excessive vomiting or diarrhoea
- gout
- systemic lupus erythematosus (SLE)
- high levels of potassium in your blood
- adrenal gland problems

You must also tell your doctor if you:

- 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)
- 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.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Some medicines may interfere with olmesartan/HCTZ. These include:

- 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, used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- potassium supplements or potassium-containing salt substitutes
- other medicines that may increase potassium levels in the blood (e.g. trimethoprim-containing products)
- lithium or antidepressant medicines
- insulin and tablets used to treat diabetes
- antacids, used to treat heartburn and indigestion
- medicines which lower your immune system (e.g. corticosteroids and cytotoxic medicines used to treat cancer, including radiation therapy)
- alcohol
- laxatives, used to treat constipation
- medicines used to relieve pain
- medicines used to treat epilepsy
- antiarrhythmics which treat irregular heart beats
- muscle relaxants
- cholestyramine and colestipol, used to treat high cholesterol.
- medicines that contain aliskiren
- any medicines that contain colesevelam

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

Other medicines not listed above may also interfere with olmesartan/HCTZ.

Your doctor and pharmacist have more information on medicines to

be careful with or avoid while taking this medicine.

Taking other medicines

The safety and effectiveness of olmesartan/HCTZ in children has not been established.

How to take this medicine

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

They may differ from the information contained in this leaflet.

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

How much to take

Your doctor will tell you how much medicine you will need to take each day, depending on your condition and if you are taking any other medicines.

The usual dose is one tablet taken once a day.

How to take it

Swallow the tablet whole with a full glass of water.

Do not chew the tablets.

When to take it

Take this medicine 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.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Olmesartan/HCTZ helps control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

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 that you missed.

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

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Australian Poisons Information Centre (telephone 13 11 26) or go to the Emergency department at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

If you take too much of olmesartan/HCTZ, you may feel light-headed, have a fast heartbeat, feel dizzy or you may faint.

While you are using this medicine

Things you must do

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking this medicine.

Make sure you drink enough water during exercise and hot weather when you are taking this medicine, especially if you sweat a lot.

If you do not drink enough water while taking this medicine, 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.

Tell your doctor if you have excess vomiting and/or diarrhoea while taking this medicine.

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 this medicine, or when your dose is increased.

Tell your doctor or dentist that you are taking this medicine if you plan to have surgery that needs a general anaesthetic, as your blood pressure may drop suddenly.

Tell your doctor immediately if you become pregnant while taking this medicine.

Tell your doctor that you are taking this medicine if you are about to have any blood tests.

Olmesartan/HCTZ may interfere with the results of some tests.

Tell your doctor if photosensitivity reactions occur during your treatment.

Tell your doctor if you develop an unexpected skin lesion during the treatment.

Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (nonmelanoma skin cancer).

Protect your skin from sun exposure and UV rays while taking this medicine.

Tell your doctor immediately in case of 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/HCTZ. This can lead to permanent vision loss, if not treated.

Tell your doctor immediately if you experience any fever, severe shortness of breath, breathing faster than normal, difficulty breathing, slightly blue fingertips and lips after taking this medicine. Stop the medication and seek medical attention immediately.

Keep all your doctor's appointments.

Your doctor may occasionally do blood tests to check your potassium levels and see how your kidneys are working, as well as to check your blood pressure.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking this medicine, or change the dosage, without checking with your doctor.

Things to be careful of

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.

Be careful driving or operating machinery until you know how this medicine affects you.

Olmesartan/HCTZ may cause dizziness, light-headedness or tiredness in some people. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

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 must 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 product, biscuits, cakes, pastries, chocolates, chips and coconut.
- 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 helps to reduce blood pressure and helps get the heart fitter. 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. Ask your doctor or pharmacist for further information and advice.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking olmesartan HCTZ.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

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

Hydrochlorothiazide, a component of this medicine, increases sensitivity of the skin to the sun and may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer).

Hydrochlorothiazide, a component of this medicine, 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).

Hydrochlorothiazide, a component of this medicine, may cause fever, severe shortness of breath, breathing faster than normal, difficulty breathing, slightly blue fingertips and lips.

As your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- feeling light-headed, dizzy, faint, or headache
- stomach problems, including nausea, vomiting, pain, diarrhoea, constipation, or an uncomfortable feeling in the stomach
- unusual tiredness or weakness, fatigue
- 'flu-like' symptoms, runny or blocked nose, sneezing, cough or bronchitis
- swelling of the hands, feet or ankles
- back pain
- urinary tract infection
- blurred vision
- skin rashes or eczema
- sleep disturbance
- depression

These are common side effects. They are generally mild.

Tell your doctor as soon as possible if you notice any of the following:

- sore throat and discomfort when swallowing (pharyngitis)
- jaundice
- skin rash or itchiness
- aching, tender or weak muscles not caused by exercise
- painful joints
- fast heartbeat
- shortness of breath or tightness in the chest

- swelling of the hands, feet or ankles
- yellowing of the whites of the eyes, dark urine and itching of the skin
- nausea, diarrhoea, muscle weakness, change in heart rhythm (symptoms that may indicate high potassium levels in the blood)

These may be serious side effects. You may need medical attention. Serious side effects are rare.

If any of the following happen, stop taking this medicine and either tell your doctor immediately or go to the Emergency department at your nearest hospital:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (signs of an allergic reaction)
- chest pain

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

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some patients.

After using this medicine

Storage

Keep your tablets in the pack until it is time to take them.

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

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the tablets have passed their expiry date, ask your pharmacist what to do with any medicine that is left over.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park, NSW 2113
Australia

This leaflet was prepared in November 2022.

Product description

What it looks like

20/12.5 mg tablets: Yellow film coated, round, biconvex tablet debossed with '346' on one side and 'L' on other side. AUST R 221116.

40/12.5 mg tablets: Yellow film coated, oval shape, biconvex tablets debossed with 'L347' on one side and plain on other side. AUST R 221118.

40/25 mg tablets: Yellow film coated, oval shape, biconvex tablets debossed with 'L348' on one side and plain on other side. AUST R 221121.

Blister pack of 30 film-coated tablets.

Ingredients

Each tablet contains either 20 mg or 40 mg of olmesartan, and either 12.5 mg or 25 mg of hydrochlorothiazide as the active ingredients.

Other ingredients include:

- lactose monohydrate
- microcrystalline cellulose
- hydroxypropylcellulose
- magnesium stearate
- Opadry Yellow 03F82788

This medicine does not contain sucrose, tartrazine or any other azo dyes.

This medicine contains sugars (as lactose).