

OLMETEC PLUS®

Olmesartan medoxomil and hydrochlorothiazide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about OLMETEC PLUS.

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 OLMETEC PLUS against the benefits he/she expects it will have for you.

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

Keep this leaflet with your OLMETEC PLUS Tablets.

You may need to read it again.

What OLMETEC PLUS is used for

OLMETEC PLUS 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.

How OLMETEC PLUS works

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

OLMETEC PLUS also contains a diuretic which reduces the amount of fluid in the body. This also helps to lower blood pressure.

Your doctor may have prescribed OLMETEC PLUS for another reason. Ask your doctor if you have any questions about why OLMETEC PLUS has been prescribed for you.

OLMETEC PLUS is not addictive.

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

Before you take OLMETEC PLUS

When you must not take it

- **Do not take OLMETEC PLUS 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 OLMETEC PLUS 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 have diabetes and are taking a medicine called aliskiren to reduce blood pressure.**

Do not take OLMETEC PLUS if you are pregnant or breastfeeding.

OLMETEC PLUS 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 OLMETEC PLUS should be discontinued as soon as possible.

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

If you are not sure whether you should start taking OLMETEC PLUS, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

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

- kidney problems

- liver problems
- heart problems
- diabetes
- excessive vomiting or diarrhoea recently
- gout
- Systemic Lupus Erythematosus (SLE)
- high levels of potassium in your blood.
- problems with your adrenal glands (small glands above the kidneys)

You must also tell your doctor if 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.

If you have not told your doctor about any of the above, tell him/her before you start taking OLMETEC PLUS.

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 and OLMETEC PLUS may interfere with each other. These include:

- other medicines used to treat high blood pressure
- other 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 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 heart beats
- muscle relaxants
- cholestyramine and colestipol, used to treat high cholesterol
- any medicine that contains aliskiren
- any medicines that contain colesevelam.

These medicines may be affected by OLMETEC PLUS, 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 OLMETEC PLUS. Your doctor and pharmacist

have more information on medicines to be careful with or avoid while taking this medicine.

Use in children

The safety and effectiveness of OLMETEC PLUS in children has not been established.

How to take OLMETEC PLUS

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

They may differ from the information contained in this leaflet.

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

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

How much to take

The dose of OLMETEC PLUS is one tablet to be taken once a day.

How to take it

Swallow OLMETEC PLUS whole with a full glass of water.

Do not chew the tablets.

When to take it

Take OLMETEC PLUS at about the same time each day, with or without food.

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

OLMETEC PLUS helps control your condition, but does not cure it. Therefore you must take OLMETEC

PLUS every day. Continue taking your medicine for as long as your doctor tells you.

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 Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much OLMETEC PLUS. Do this even if there are no signs of discomfort or poisoning.

Keep telephone numbers for these places handy.

If you take too much OLMETEC PLUS, you may feel light-headed, dizzy or you may faint. You may also have a fast heart beat.

While you are using OLMETEC PLUS

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 OLMETEC PLUS.

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

If you do not drink enough water while taking OLMETEC PLUS, 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 have excess vomiting and/or diarrhoea, while taking OLMETEC PLUS, tell your doctor.

You may lose too much water and salt and your blood pressure may drop too much.

If you feel light-headed or dizzy after taking your first dose of OLMETEC PLUS, or when your dose is increased, tell your doctor immediately.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking OLMETEC PLUS.

Your blood pressure may drop suddenly.

If you become pregnant while taking OLMETEC PLUS, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking OLMETEC PLUS.

OLMETEC PLUS may interfere with the results of some tests.

Tell your doctor if photosensitivity reaction occurs during your treatment.

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 OLMETEC PLUS. 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 OLMETEC PLUS. Stop the medication and seek medical attention immediately.

Have your blood pressure checked when your doctor says, to make sure OLMETEC PLUS 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.

Things you must not do

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

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

Do not stop taking OLMETEC PLUS, or lower 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 OLMETEC PLUS affects you.

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

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.

Side effects

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

OLMETEC PLUS helps most people with high blood pressure, but it may have unwanted side effects in a few people. 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.

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.

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

The following is a list of possible side effects. Do not be alarmed by this list. 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 or faint
- cough
- headache
- feeling sick (nausea) or vomiting
- stomach pain
- diarrhoea or constipation
- an uncomfortable feeling in the stomach
- unusual tiredness or weakness, fatigue
- 'flu-like' symptoms
- runny or blocked nose, or sneezing
- bronchitis
- sore throat and discomfort when swallowing (pharyngitis)
- swelling of the hands, feet or ankles
- back pain
- urinary tract infection
- jaundice
- 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:

- skin rash or itchiness
- aching, tender or weak muscles not caused by exercise
- painful joints
- fast heart beat
- 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.
- symptoms that may indicate high potassium levels in the blood, such as nausea, diarrhoea, muscle

weakness, change in heart rhythm.

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

If any of the following happen, stop taking OLMETEC PLUS and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- chest pain.

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

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using OLMETEC PLUS

Storage

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.

Do not store OLMETEC PLUS 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 OLMETEC PLUS or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

OLMETEC PLUS tablets come in four strengths and each has a different appearance:

OLMETEC PLUS 20/12.5mg is a round tablet, approximately 8.5mm in diameter, reddish yellow in colour with C22 debossed on one side.

OLMETEC PLUS 20/25 mg is a round tablet, approximately 8.5 mm in diameter, pinkish in colour with C24 debossed on one side. Not currently available in Australia.

OLMETEC PLUS 40/12.5mg is an oval tablet, approximately 15mm x 7mm, reddish yellow in colour with C23 debossed on one side.

OLMETEC PLUS 40/25mg is an oval tablet, approximately 15mm x 7mm in diameter, pinkish in colour with C25 debossed on one side.

The product is presented in blister packs of 10 or 30 film-coated tablets.

Ingredients

Active ingredients:

OLMETEC PLUS 20/12.5 - 20mg olmesartan medoxomil and 12.5mg hydrochlorothiazide

OLMETEC PLUS 20/25 - 20mg olmesartan medoxomil and 25 mg hydrochlorothiazide

OLMETEC PLUS 40/12.5 - 40mg olmesartan medoxomil and 12.5mg hydrochlorothiazide

OLMETEC PLUS 40/25 - 40mg olmesartan medoxomil and 25mg hydrochlorothiazide

Other ingredients:

- microcrystalline cellulose

- lactose monohydrate
- hypromellose
- magnesium stearate
- and Opadry O2A22352 or Opadry O2A24576 that contain titanium dioxide, purified talc, hypromellose and iron oxides.

OLMETEC PLUS does not contain sucrose, tartrazine or any other azo dyes.

Supplier

OLMETEC PLUS is supplied in Australia by:

Organon Pharma Pty Ltd
Building A, 26 Talavera Road,
Macquarie Park NSW 2113

Australian Registration Numbers

OLMETEC PLUS 20/12.5

AUST R 115738

OLMETEC PLUS 20/25

AUST R 115732

OLMETEC PLUS 40/12.5

AUST R 115737

OLMETEC PLUS 40/25

AUST R 115661

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