OLMETEC®

Olmesartan medoxomil (20 mg, 40 mg)

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What Olmetec is used for

Olmetec is used to treat high blood pressure.

How Olmetec works

Olmetec belongs to a group of medicines called angiotensin-II receptor antagonists. It lowers blood pressure by relaxing the blood vessels.

Before you use Olmetec

- *When you must not use it*

Do not take Olmetec if you:

- are allergic to olmesartan medoxomil or to any of the other ingredients of Olmetec.
- are in the second and third trimesters of pregnancy.
- suffer from problems with drainage of the bile from the gallbladder (biliary obstruction).
- have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Pregnancy and lactation

Do not take Olmetec if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Olmetec if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- *Before you start use it*

Before you take Olmetec, tell your doctor if you:

- have diarrhoea, vomiting, or you are on a treatment with high doses of diuretics or on a low salt diet
- are taking medicinal products that affect the renin-angiotensin-aldosterone system
- have kidney problems or have had a recent kidney transplant
- have liver disease
- have high potassium levels in blood
- are using medicinal products made of ACE-inhibitors, angiotensin II receptor blockers, aliskiren, or lithium
- have heart failure or problems with your heart valves or heart muscles
- have Conn's syndrome (excess production of aldosterone)
- have galactose intolerance, Lapp-lactase deficiency or glucose-galactose malabsorption

- *Taking other medicines*

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

- Potassium supplements, salt substitutes which contain potassium, potassium-sparing diuretics or heparin (for thinning the blood). Using these medicines at the same time as Olmetec may raise the levels of potassium in your blood.
- Lithium (a medicine used to treat mood swings and some types of depression) used at the same time as Olmetec may increase the toxicity of lithium. If you have to take lithium, your doctor will measure your lithium blood levels.
- Non-Steroidal Anti-Inflammatory (NSAIDs) medicines (medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis) used at the same time as Olmetec may increase the risk of kidney failure and the effect of Olmetec can be decreased by NSAIDs.
- Other blood pressure lowering medicines (ACE-inhibitors, angiotensin II receptor blockers or aliskiren), as the effect of Olmetec can be increased.
- Certain antacids (indigestion remedies), as the effect of Olmetec can be slightly decreased.
- Colesevelam hydrochloride, a drug that lowers the level of cholesterol in your blood, as the effect of Olmetec may be decreased. Your doctor may advise you to take Olmetec at least 4 hours before colesevelam hydrochloride.

How to use Olmetec

- *How much to use*

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The recommended starting dose is 20 mg tablet once a day. However, if your blood pressure is not controlled, your doctor may change your dose up to 40 mg once a day, or prescribe additional medicines.

In patients with mild to moderate kidney disease or moderate liver disease, dose should not be higher than 20 mg once a day.

The tablet can be taken at about the same time each day, with or without food. The tablet should be swallowed with a sufficient amount of fluid (e.g. one glass of water). The tablet should not be chewed.

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

Continue taking Olmetec for as long as your doctor recommends.

- *If you forget to use it*

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause low blood pressure.

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Olmetec.

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

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Olmetec to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Olmetec. Your doctor will decide on further treatment. Do not stop taking Olmetec on your own.

Children and adolescents (under 18)

Olmetec is not recommended for children and adolescents under the age of 18.

Black patients

As with other similar drugs the blood pressure lowering effect of Olmetec is somewhat less in black patients.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Olmetec can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine, especially any of the following:

Common side effects (may affect up to 1 in 10 people)

- Increased fat levels
- Increased uric acid levels
- Dizziness
- Headache
- Inflammation of bronchial tubes
- Swelling of pharynx
- Cough
- Runny or stuffy nose
- Gastroenteritis
- Diarrhoea
- Stomach ache
- Nausea
- Indigestion
- Joint inflammation
- Pain in the chest, back, bones or joints
- Blood in the urine
- Changes in blood test results (increased fat levels, increased uric acid levels, increases in tests of liver and muscle function)
- Tiredness
- Sore throat
- Flu-like symptoms
- Infection of the urinary tract
- Swelling of ankles, feet, legs, hands, or arms

Uncommon side effects (may affect up to 1 in 100 people)

- Quick allergic reactions that may affect the whole body and may cause breathing problems as well as a rapid fall of blood pressure that may even lead to fainting (anaphylactic reactions)
- Vertigo
- Pain or uncomfortable feeling in the chest (angina)
- Vomiting
- Skin rash, allergic skin rash, itching, exanthema (skin eruption), itchy rash (urticaria)
- Muscular pain
- Swelling of the face
- Weakness, feeling unwell
- Reduction of platelet number in blood test result (thrombocytopenia)

Rare side effects (may affect up to 1 in 1,000 people)

- Low blood pressure
- Rapid swelling under the skin in areas such as the face, throat, arms and legs which can be life threatening if throat swelling blocks the airway (angioedema)
- Muscle cramps
- Impaired kidney function, kidney failure.
- Lack of energy
- Changes in blood test results [increased potassium levels (hyperkalaemia) and increased levels of compounds related to kidney function]Intestinal

angioedema (a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea)

Very rare side effects (may affect up to 1 in 10,000 people)

- Sprue-like enteropathy (diarrhea in combination with previous findings of abnormal villous architecture of the small intestine)

Frequency not known

- Autoimmune inflammation of the liver

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Olmetec

- *Storage*

Keep out of the reach and sight of children.

Store below 30°C.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

Olmetec 20 mg tablet: White, circular film coated tablet with characteristic odour approximately 8.5 mm in diameter, with C14 embossed on one side.

Olmetec 40 mg tablet: White, oval film coated tablet with characteristic odour approximately 15 x 7 mm in size, with C15 embossed on one side.

- *Ingredients*
  - Active ingredient:
    Olmesartan medoxomil
  - Inactive ingredients:
    Tablet core
    Cellulose, microcrystalline
    Lactose monohydrate
    Hydroxypropylcellulose
    Low substituted hydroxypropylcellulose
    Magnesium stearate

    Tablet coat
    Titanium dioxide (E 171)
    Talc
    Hypromellose

- *MAL numbers:*

Product Name	Registration Number
Olmetec 20 mg Film-coated Tablet	MAL20051374 ACRZ
Olmetec 40 mg Film-coated Tablet	MAL20051373 ACRZ

Manufacturer
Daiichi Sankyo Europe GmbH
Luitpoldstrasse 1, D-85276,
Pfaffenhofen, Germany.

Product Registration Holder
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