

Olmecord 20, 40

Olmesartan Medoxomil Film-Coated Tablets USP 20mg, 40 mg

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What Olmecord is used for

Olmecord is used to treat high blood pressure.

How Olmecord works

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

Before you use Olmecord

- When you must not use it

Do not take Olmecord if you:

- are allergic to Olmecord medoxomil or to any of the other ingredients of Olmecord.
- 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 Olmecord if you are pregnant, trying to get pregnant or think you may be pregnant.

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

- Before you start use it

Before you take Olmecord, 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 Olmesartan 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 Olmecord 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 Olmecord may increase the risk of kidney failure and the effect of Olmecord can be decreased by NSAIDs.

- Other blood pressure lowering medicines (ACE-inhibitors, angiotensin II receptor blockers or aliskiren), as the effect of Olmecord can be increased.
- Certain antacids (indigestion remedies), as the effect of Olmecord can be slightly decreased.
- Colesevelam hydrochloride, a drug that lowers the level of cholesterol in your blood, as the effect of Olmesartan may be decreased. Your doctor may advise you to take Olmecord at least 4 hours before colesevelam hydrochloride

How to use Olmecord

- 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

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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 Olmecord 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 Olmecord.

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 Olmecord to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Children and adolescents (under 18)

Olmecord 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 Olmecord 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, Olmecord 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.)

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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]

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 Olmecord

- 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

Olmecord 20:

White to off-white, round, biconvex, film coated tablets, debossed with "IO3" on one side and plain on other side.

Olmecord 40: White to off-white, oval, biconvex, film coated tablets, debossed with "IO4" on one side and plain on other side.

- Ingredients

- Active ingredient: Olmesartan medoxomil

- Inactive ingredients:

Tablet core

Lactose monohydrate
Hydroxypropylcellulose
Microcrystalline Cellulose
Magnesium stearate
Low-substituted hydroxypropyl cellulose LH-21
Isopropyl alcohol

- Coating

Talc
Hypromellose
Titanium dioxide (E171)
Hypromellose 6CPS
Purified Talc
Titanium dioxide
Isopropyl alcohol
Dichloromethane

- MAL numbers:

Olmecord 20:

Olmecord 40:

Manufacturer

Intas Pharmaceuticals Ltd.
Plot Number 457-458 & 191/218P,
Sarkhej-Bavla Highway, Matoda,
Sanand Ahmedabad, Gujarat, 382
210, INDIA

Product registration holder & importer:

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