

VOTUM[®] 10 mg, 20 mg, 40 mg

Film-Coated Tablets

olmesartan medoxomil

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What is Votum and what it is used for

Votum belongs to a group of medicines called angiotensin-II receptor antagonists. They lower blood pressure by relaxing the blood vessels.

Votum is used for the treatment of high blood pressure (also known as 'hypertension'). High blood pressure can damage blood vessels in organs such as the heart, kidneys, brain and eyes. In some cases this may lead to a heart attack, heart or kidney failure, stroke or blindness. Usually high blood pressure has no symptoms. It is important to have your blood pressure checked to prevent damage occurring.

High blood pressure can be controlled with medicines such as Votum tablets. Your doctor has probably also recommended that you make some changes in your lifestyle to help lower your blood pressure (for example losing weight, giving up smoking, reducing the amount of alcohol you drink and reducing the amount of salt in your diet). Your doctor may also have urged you to take regular exercise, such as walking or swimming. It is important to follow this advice from your doctor.

Taking Votum with food and drink

Votum can be taken with or without food. Swallow the tablets with a little water. If possible, take your daily dose at the same time each day, for example at breakfast time.

Children and adolescents (under 18)

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

Elderly patients

If you are over 65 years of age and your doctor decides to increase your dose of olmesartan medoxomil to 40 mg daily, then you need to have your blood pressure regularly checked by your doctor to make sure that your blood pressure does not become too low.

Black patients

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

Pregnancy and breastfeeding Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Votum before you become pregnant or as soon as you know you are pregnant and will advise you to take

advice from your doctor.

2. Before you take Votum

Do not take Votum

- if you are allergic (hypersensitive) to olmesartan medoxomil or to any other of the ingredients of Votum
- if you are more than 3 months pregnant. (It is also better to avoid Votum tablets in early pregnancy – see pregnancy section.)
- if you suffer from yellowing of the skin and eyes (jaundice) or problems with drainage of the bile from the gallbladder (biliary obstruction e.g. gallstones).

Take special care with Votum

Before you take the tablets, **tell your doctor** if you have any of the following health problems:

- Kidney problems
- Liver disease
- Heart failure or problems with your heart valves or heart muscle.
- Severe vomiting, diarrhoea, treatment with high doses of water tablets (diuretics) or if you are on a low salt diet.
- Increased levels of potassium in your blood.
- Problems with your adrenal glands.

As with any medicine which reduces blood pressure, an excessive drop in blood pressure in patients with blood flow disturbances of the heart or brain could lead to a heart attack or stroke. Your doctor will therefore check your blood pressure carefully.

stop taking Votum before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Votum. Votum is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breastfeeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Votum is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

It is unlikely that Votum will affect your ability to drive or operate machinery. However, dizziness or fatigue can occasionally occur during the treatment of high blood pressure. If you notice such effects, do not drive or use machines until the symptoms wear off. Ask your doctor for advice.

Important information about some of the ingredients in Votum

This medicine contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

You must tell your doctor if you think you are (or might become) pregnant. Votum is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines:

- Potassium supplements, a salt substitute which contains potassium, water tablets (diuretics) or heparin (for thinning the blood). Using these medicines at the same time as Votum 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 Votum 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 Votum may increase the risk of kidney failure and the effect of Votum can be decreased by NSAIDs.
- Other blood pressure lowering medicines, as the effect of Votum can be increased.
- Certain antacids (indigestion remedies), as the effect of Votum can be slightly decreased.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. How to take Votum

Always take Votum exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets can be taken with or without food. Swallow the tablets with a little water. If possible, take your daily dose at the same time each day, for example at breakfast time.

The usual starting dose is one 10 mg tablet once a day. However, if your blood pressure is not controlled, your doctor may decide to change your dose up to 20 or 40 mg once a day, or prescribe additional medicines.

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

If you take more Votum than you should

If you take more tablets than you should or if a child accidentally swallows some, go to your doctor or nearest emergency department immediately and take your medicine pack with you.

If you forget to take Votum

If you forget a dose, take your normal dose on the following day as usual. Do **not** take any extra tablets to make up for the missed dose.

If you stop taking Votum

It is important to continue to take Votum unless your doctor tells you to stop.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Votum can cause side effects, although not everybody gets them. If they do occur, they are often mild and do not require treatment to be stopped.

Although not many people may get them, the following two side effects can be serious:

On very rare occasions the following allergic reactions have been reported:

Swelling of the face, mouth and/or larynx (voice box) together with itching and rash may occur during treatment with Votum. **If this happens stop taking Votum and contact your doctor immediately.**

Rarely (but slightly more often in elderly patients) Votum can cause the blood pressure to fall too low in susceptible individuals. This could cause severe light-headedness or fainting. **If this occurs stop taking Votum, contact your doctor immediately and lie down flat.**

To give you an idea of how many patients might get side effects, they have been listed as common, uncommon, rare and very rare. These mean the following:

Common	less than 1 in 10 people.
Uncommon	less than 1 in 100 people.
Rare	less than 1 in 1,000 people.
Very rare	less than 1 in 10,000 people.

Common side effects:

Dizziness, nausea, indigestion, diarrhoea, stomach ache, gastroenteritis, tiredness, sore throat, runny or stuffy nose, bronchitis, flu-like symptoms, cough, pain in the chest, back, bones or joints, infection of the urinary tract, swelling of ankles, feet, legs, hands, or arms, blood in the urine.

Some changes in blood test results have also been seen and include the following:

increased fat levels (hypertriglyceridaemia), increased uric acid levels (hyperuricaemia), increases in tests of liver and muscle function.

Uncommon side effects:

Vertigo, skin rash, angina (pain or uncomfortable feeling in the chest).

Rare side effects:

Rarely, blood test results have shown increased potassium levels (hyperkalaemia).

Votum 40 mg film-coated tablets are white, oval with C 15 on one side.

Votum film-coated tablets are available in packs of 14, 28, 30, 56, 84, 90, 98 and 10 x 28 film-coated tablets and in packs with perforated unit dose blisters of 10, 50 and 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Menarini International Operations Luxembourg S.A.

1, Avenue de la Gare L-1611 Luxembourg

Manufacturer

Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276 Pfaffenhofen, Germany

or alternatively

BERLIN-CHEMIE AG, Glienicker Weg 125, D-12489 Berlin, Germany

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Rare side effects:

Rarely, blood test results have shown increased potassium levels (hyperkalaemia).

Very rare side effects:

Headache, muscle cramps and muscular pain, impaired kidney function, kidney failure, weakness, lack of energy, feeling unwell, vomiting, itching, exanthema (skin eruption).

Some changes in blood test results have also been seen. These include increased levels of compounds related to kidney function and reduced numbers of a type of blood cell, known as platelets (thrombocytopenia).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Votum

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use Votum after the expiry date ("EXP") which is stated on the box and on the blister strip. The expiry date refers to the last day of that month.

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.

6. Further information

What Votum contains

The active substance is olmesartan medoxomil

Each film-coated tablet contains 10 mg, 20 mg or 40 mg olmesartan medoxomil.

Other ingredients are

microcrystalline cellulose, lactose monohydrate, hydroxypropylcellulose, low substituted hydroxypropylcellulose, magnesium stearate, titanium dioxide (E171), talc and hypromellose.

What Votum looks like and contents of the pack

Votum 10 mg film-coated tablets are white, circular with C 13 on one side.

Votum 20 mg film-coated tablets are white, circular with C 14 on one side.

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Menarini International Operations Luxembourg S.A.
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