

Votum Plus 20 mg/12.5 mg

Votum Plus 20 mg/25 mg

Film-coated tablets

olmesartan medoxomil/hydrochlorothiazide

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 on 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.

In this leaflet:

1. What Votum Plus is and what it is used for
2. Before you take Votum Plus
3. How to take Votum Plus
4. Possible side effects
5. How to store Votum Plus
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1. What Votum Plus is and what it is used for

Votum Plus contains two active substances, olmesartan medoxomil and hydrochlorothiazide, that are used to treat high blood pressure (hypertension):

- Olmesartan medoxomil is one of a group of medicines called angiotensin II-receptor antagonists. It lowers blood pressure by relaxing the blood vessels.
- Hydrochlorothiazide is one of a group of medicines called thiazide diuretics ("water tablets"). It lowers blood pressure by helping the body to get rid of extra fluid by making your kidneys produce more urine.

You will only be given Votum Plus if Olmetec (olmesartan medoxomil) alone has not adequately controlled your blood pressure. When given together, the two active substances in Votum Plus help to lower blood pressure more than if either of them were given alone.

You may already be taking medicines to treat your high blood pressure, but your doctor may want you to take Votum Plus to lower it more.

High blood pressure can be controlled with medicines such as Votum Plus 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.

2. Before you take Votum Plus

Do not take Votum Plus if you:

- are allergic (hypersensitive) to olmesartan medoxomil or to hydrochlorothiazide, or to any of the other ingredients in the tablets (Section 6 contains a complete list) or to substances similar to hydrochlorothiazide (sulfonamides)
- are more than 3 months pregnant (It is also better to avoid Votum Plus in early pregnancy – see pregnancy section.)
- have severe kidney problems
- suffer from low potassium, low sodium, high calcium or high uric acid levels in the blood (with symptoms of gout or kidney stones) that do not get better when treated
- suffer from severe liver problems or yellowing of the skin and eyes (jaundice) or problems with drainage of the bile from the gallbladder (biliary obstruction e.g. gallstones)

If you think any of these apply to you, or you are unsure, do not take the tablets. Talk to your doctor first and follow the advice given.

Take special care with Votum Plus

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

- Mild to moderate kidney problems or if you have had a recent kidney transplant
- Liver diseases
- Heart failure or problems with your heart valves or heart muscles
- Vomiting (being sick) or diarrhoea which is severe or it goes on for several days
- Treatment with high doses of water tablets (diuretics) or if you are on a low salt diet
- Problems with your adrenal glands (e.g. primary aldosteronism)
- Diabetes
- Lupus erythematosus (an autoimmune disease)
- Allergies or asthma.

Your doctor may want to see you more often and do some tests if you have any of these conditions.

Votum Plus may cause a rise in blood fat levels and uric acid levels (the cause of gout – painful swelling of the joints). Your doctor will probably want to do a blood test from time to time to check these.

It may change the levels of certain chemicals in your blood called electrolytes. Your doctor will probably want to do a blood test from time to time to check these. Signs of electrolyte changes are: thirst, dryness of the mouth, muscle pain or cramps, tired muscles, low blood pressure (hypotension), feeling weak, sluggish, tired, sleepy or restless, nausea, vomiting, less need to pass urine, a rapid heart rate. **Tell your doctor if you notice these symptoms.**

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.

If you are due to have tests for parathyroid function, you should stop taking Votum Plus before these tests are carried out.

If you are a sports person, this medicine could change the results of an anti-dope test to make it positive.

You must tell your doctor if you think that you are (or might become) pregnant. Votum Plus 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 other medicines including medicines obtained without a prescription.

In particular, tell your doctor or pharmacist about any of the following:

- Medicines which may raise the levels of potassium in your blood if used at the same time as Votum Plus. These include:
 - potassium supplements (as well as salt substitutes containing potassium)
 - water tablets (diuretics)
 - heparin (for thinning the blood)
 - laxatives
 - steroids
 - adrenocorticotrophic hormone (ACTH)
 - carbenoxolone (a medicine used to treat mouth and stomach ulcers)
 - penicillin G sodium (also called benzylpenicillin sodium, an antibiotic)
 - certain pain killers such as aspirin or salicylates
- Lithium (a medicine used to treat mood swings and some types of depression) used at the same time as Votum Plus 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 Plus may increase the risk of kidney failure and the effect of Votum Plus can be decreased by NSAIDs
- Other blood pressure lowering medicines (anti-hypertensives), as the effect of Votum Plus can be increased
- Sleeping tablets, sedatives and anti-depressant medicines, as using these medicines together with Votum Plus may cause a sudden drop in blood pressure when standing up
- Certain medicines such as baclofen and tubocurarine, used to relax muscles
- Amifostine and some other drugs used to treat cancers, such as cyclophosphamide or methotrexate
- Colestyramine and colestipol, medicines for lowering blood fat levels
- Anticholinergic agents, such as atropine and biperiden
- Drugs such as thioridazine, chlorpromazine, levomepromazine, trifluoperazine, cyamemazine, sulpiride, amisulpride, pimozone, sultopride, tiapride, droperidol or haloperidol, used to treat certain psychiatric disorders
- Certain medicines such as quinidine, hydroquinidine, disopyramide, amiodarone, sotalol or digitalis, used to treat heart problems
- Medicines such as mizolastine, pentamidine, terfenadine, dofetilide, ibutilide or erythromycin injections, which may change the heart rhythm
- Oral anti-diabetic medicines, such as metformin or insulin, used to lower blood sugar
- Beta-blockers and diazoxide, medicines used to treat high blood pressure or low blood sugar, respectively, as Votum Plus can enhance their blood-sugar-increasing effect
- Methylodopa, a medicine used to treat high blood pressure
- Medicines such as noradrenaline, used to increase blood pressure and slow heart rate
- Diphemanil, used to treat a slow heartbeat or reduce sweating
- Medicines such as probenecid, sulfapyrazone and allopurinol, used to treat gout
- Calcium supplements
- Amantadine, an anti-viral drug
- Ciclosporin, a medicine used to stop rejection of organ transplants
- Certain antibiotics called tetracyclines or sparflaxacin
- Amphotericin, a medicine used to treat fungal infections
- Certain antacids, used to treat too much stomach acid, such as aluminium magnesium hydroxide, as the effect of Votum Plus can be slightly decreased
- Cisapride, used to increase food movement in the stomach and gut
- Halofantrine, used for malaria.

Taking Votum Plus with food and drink

Votum Plus can be taken with or without food.

Take care when drinking alcohol while you are taking Votum Plus, as some people feel faint or dizzy. If this happens to you, do not drink any alcohol, including wine, beer or alcopops.

Children and adolescents (under 18)

Votum Plus 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 Votum Plus is somewhat less in black patients.

Pregnancy and breast-feeding

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

Breastfeeding

Tell your doctor if you are breastfeeding or about to start breastfeeding. Votum Plus is not recommended for mothers who are breastfeeding, and your doctor may choose another treatment for you if you wish to breastfeed.

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

Driving and using machines

You may feel sleepy or dizzy while being treated for your high blood pressure. If this happens, do not drive or use machines until the symptoms wear off. Ask your doctor for advice.

Important information about some of the ingredients of Votum Plus

Lactose:

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 medicine.

3. How to take Votum Plus

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

The usual dose is one Votum Plus 20 mg/12.5 mg tablet a day. However, if your blood pressure is not controlled, your doctor may decide to change your dose to one Votum Plus 20 mg/25 mg tablet a day.

Swallow the tablet with water. If possible, you should take your dose **at the same time each day**, for example at breakfast time. It is important to continue to take Votum Plus until your doctor tells you to stop.

Registrazione prodotto

Prodotto F.I. Votum Plus 20/12.5 20/25mg Paese Libano

n.id 0001/12 v01

Sito Produttivo B/C F.to/Dim. 148x630 mm

Colori: nero

Data 19/03/12

Operatore Picconcelli

If you take more Votum Plus than you should

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

If you forget to take Votum Plus

If you forget to take 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 Plus

It is important to continue to take Votum Plus 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 Plus can cause side effects, although not everybody gets them.

However, the following two side effects can be serious:

- Allergic reactions that may affect the whole body, with swelling of the face, mouth and/or voice box (larynx) together with itching and rash may occur rarely. **If this happens, stop taking Votum Plus and contact your doctor immediately.**
- Votum Plus can cause the blood pressure to fall too low in susceptible individuals or as the result of an allergic reaction. Light-headedness or fainting may occur uncommonly. **If this happens, stop taking Votum Plus, contact your doctor immediately and lie down flat.**

Votum Plus is a combination of two active substances and the following information firstly gives the other side effects reported so far with the combination Votum Plus (besides those already mentioned above) and, secondly, those which are known about for the separate active substances.

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	affects less than 1 in 10 patients
Uncommon	affects less than 1 in 100 patients
Rare	affects less than 1 in 1,000 patients
Very rare	affects less than 1 in 10,000 patients

These are the other side effects known about so far with Votum Plus:

If these side effects occur, they are often mild and **you do not need to stop your treatment.**

Common side effects:

Dizziness, weakness, headache, tiredness, chest pain, swelling of ankles, feet, legs, hands or arms.

Uncommon side effects:

Fluttering of the heart beat (palpitations), rash, eczema, vertigo, cough, indigestion, abdominal pain, nausea, vomiting, diarrhoea, muscle cramps and muscular pain, pain in joints, arms and legs, back pain, erection difficulties in men, blood in urine.

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

Rise in blood fat levels, rise in blood urea or uric acid, rise in creatinine, rise or decrease in blood potassium levels, rise in blood calcium levels, rise in blood sugar, increase in levels of liver function. Your doctor will know about these from a blood test and will tell you if you need to do anything.

Rare side effects:

Feeling unwell, disturbances in consciousness, skin lumps (wheals), acute kidney failure.

Some changes in blood test results have also been seen in rare cases and include:

Rise in blood urea nitrogen, decrease in haemoglobin and haematocrit values. Your doctor will know about these from a blood test and will tell you if you need to do anything.

Further side effects reported with use of olmesartan medoxomil or hydrochlorothiazide alone, but not with Votum Plus or in a higher frequency:

Olmesartan medoxomil:

Common side effects:

Bronchitis, cough, runny or stuffy nose, sore throat, abdominal pain, indigestion, diarrhoea, nausea, gastroenteritis, pain in the joints or bones, back pain, blood in urine, urinary tract infection, flu-like symptoms, pain.

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

Rise in blood fat levels, rise in blood urea or uric acid, increase in levels of liver and muscle function,

Uncommon side effects:

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), swelling of the face, angina (pain or uncomfortable feeling in the chest; known as angina pectoris), feeling unwell, allergic skin rash, itching, exanthema (skin eruption), skin lumps (wheals).

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

Reduced numbers of a type of blood cell, known as platelets (thrombocytopenia).

Rare side effects:

Impaired kidney function, lack of energy.

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

Increase in blood potassium.

Hydrochlorothiazide:

Very common side effects:

Changes in blood results including: Increase in blood fat and uric acid levels.

Common side effects:

Feeling confused, abdominal pain, stomach upset, bloated feeling, diarrhoea, nausea, vomiting, constipation, excretion of glucose into the urine.

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

Increase in blood creatinine, urea, calcium and sugar levels, decrease in blood chloride, potassium, magnesium and sodium levels. Increase of serum amylase (hyperamylasaemia)

Uncommon side effects:

Decreased or loss of appetite, severe difficulty breathing, anaphylactic skin reactions (hypersensitivity reactions), worsening of pre-existing myopia, erythema, skin reactions to light itching, purplish spots or patches on the skin due to small haemorrhages (purpura), skin lumps (wheals).

Rare side effects:

Swollen and sore salivary glands, decreased number of white blood cells, decreased number of blood platelets, anaemia, bone marrow damage, restlessness, feeling 'down' or depressed, problems sleeping, feeling un-interested (apathy), tingling and numbness, fits (convulsions), objects you look at appearing yellow, blurred vision, dry eyes, irregular heart beat, inflammation of the blood vessels, blood clots (thrombosis or embolism), inflammation of the lung, fluid accumulation in the lungs, inflammation of the pancreas, jaundice, infection in the gall bladder, symptoms of lupus erythematosus such as rash, joint pains and cold hands and fingers, allergic skin reactions, peeling and blistering of the skin, non-infectious inflammation of the kidney (interstitial nephritis), fever, muscle weakness (sometimes causing impaired movement).

Very rare side effects:

Electrolyte disturbance leading to an abnormally depleted level of chloride in the blood (hypochloroemic alkalosis), blockage in the gut (paralytic ileus).

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 Plus

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use Votum Plus after the expiry date which is stated on the carton and on the blister strip as EXP. 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 Plus contains

The active substances are:

Votum Plus 20 mg/12.5 mg: Each film-coated tablet contains 20 mg olmesartan medoxomil and 12.5 mg hydrochlorothiazide.

Votum Plus 20 mg/25 mg: Each film-coated tablet contains 20 mg olmesartan medoxomil and 25 mg hydrochlorothiazide.

The other ingredients are:

Microcrystalline cellulose, lactose monohydrate*, low substituted hypromellose, hypromellose, magnesium stearate, titanium dioxide (E 171), talc, hypromellose, iron (III) oxides (E 172).

* See 'Important information about some of the ingredients of Votum Plus' section above

What Votum Plus looks like and contents of the pack:

Votum Plus 20 mg/12.5 mg film-coated tablets are reddish-yellow, round with "C22" on one side.

Votum Plus 20 mg/25 mg film-coated tablets are pinkish, round with "C24" on one side.

They 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.
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L-1611 Luxembourg
Luxembourg

Manufacturer:

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