Package leaflet: Information for the user

Olmenor Combi 40 mg/5 mg film-coated tablets
olmesartan medoxomil / amlodipine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only**. Do not pass it onto others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Olmenor Combi is and what it is used for
2. What you need to know before you take Olmenor Combi
3. How to take Olmenor Combi
4. Possible side effects
5. How to store Olmenor Combi
6. Contents of the pack and other information

1. What Olmenor Combi is and what it is used for

Olmenor Combi contains two substances called olmesartan medoxomil and amlodipine (as amlodipine besylate). Both of these substances help to control high blood pressure.

- Olmesartan belongs to a group of medicines called "angiotensin-II receptor antagonists" which lower blood pressure by relaxing the blood vessels.
- Amlodipine belongs to a group of substances called "calcium channel blockers". Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening thereby also reducing blood pressure.

The actions of both these substances contribute to stopping the tightening of blood vessels, so that blood vessels relax and blood pressure decreases.

Olmenor Combi is used to treat high blood pressure in adults whose blood pressure is not controlled enough with either olmesartan or amlodipine alone.

2. What you need to know before you take Olmenor Combi

Do not take Olmenor Combi
- If you are allergic to olmesartan, to amlodipine or a special group of calcium channel blockers, the dihydropyridines, or to any of the other ingredients of this medicine (listed in section 6).
  If you think you may be allergic, talk to your doctor before taking Olmenor Combi.
- If you are more than 3 months pregnant. It is also better to avoid Olmenor Combi tablets in early pregnancy (see section "Pregnancy and breast-feeding").

- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- If you have severe liver problems, if bile secretion is impaired or drainage of bile from the gallbladder is blocked (e.g. by gallstones), or if you are experiencing any jaundice (yellowing of the skin and eyes).
- If you have very low blood pressure.
- If you are suffering from insufficient blood supply to your tissues with symptoms like low blood pressure, low pulse, fast heartbeat (shock, including cardiogenic shock). Cardiogenic shock means shock due to severe heart troubles.
- If the blood flow from your heart is obstructed (e.g. because of the narrowing of the aorta (aortic stenosis)).
- If you suffer from low heart output (resulting in shortness of breath or peripheral swellings) after a heart attack (acute myocardial infarction).

Warnings and precautions

Talk to your doctor or pharmacist before using Olmenor Combi.

Tell your doctor if you are taking any of the following medicines to treat high blood pressure (hypertension):
- an ACE inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
- aliskiren.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading "Do not take Olmenor Combi".

Tell your doctor if you have any of the following health problems:
- Kidney problems or a kidney transplant.
- Liver disease.
- Heart failure or problems with your heart valves or heart muscle.
- Severe vomiting, diarrhea, 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 (hormone-producing glands on top of the kidneys).

Contact your doctor if you experience diarrhea that is severe, persistent and causes substantial weight loss. Your doctor may evaluate your symptoms and decide on how to continue your blood pressure medication.

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.

You must tell your doctor if you think you are or might become pregnant. Olmenor Combi 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 section Pregnancy and breast-feeding).

Children and adolescents (under 18 years of age)

Olmenor Combi is not recommended for children and adolescents under 18 years of age.

Other medicines and Olmenor Combi

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

- **Other blood pressure lowering medicines**, as the effect of Olmenor Combi can be increased. Your doctor may need to change your dose and/or to take other precautions:
  If you are taking an ACE-inhibitor or aliskiren (see also information under the headings "Do not take Olmenor Combi" and "Warnings and precautions").
- **Potassium supplements, salt substitutes containing potassium, "water tablets"** (diuretics) or **heparin** (for thinning the blood and prevention of blood clots). Using these medicines at the same time as Olmenor Combi 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 Olmenor Combi may increase the toxicity of lithium. If you have to take lithium, your doctor will measure your lithium blood levels.
- **Non-steroidal anti-inflammatory drugs** (NSAIDs, medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis) used at the same time as Olmenor Combi may increase the risk of kidney failure. The effect of Olmenor Combi can be decreased by NSAIDs.
- **Colesevelam hydrochloride**, a drug that lowers the level of cholesterol in your blood, as the effect of Olmenor Combi may be decreased. Your doctor may advise you to take Olmenor Combi at least 4 hours before colesevelam hydrochloride.
- **Certain antacids** (indigestion or heartburn remedies), as the effect of Olmenor Combi can be slightly decreased.
- **Medicines used for HIV/AIDS** (e.g. ritonavir, indinavir, nelfinavir) **or for the treatment of fungal infections** (e.g. ketoconazole, itraconazole).
- **Diltiazem**, verapamil, (agents used for heart rhythm problems and high blood pressure).
- **Rifampicin**, erythromycin, clarithromycin (antibiotics).
- **St. John's Wort** (Hypericum perforatum), a herbal remedy.
- **Dantrolene** (infusion for severe body temperature abnormalities).
- **Simvastatine**, an agent used to lower levels of cholesterol and fats (triglycerides) in the blood.
- **Tacrolimus, cyclosporine,** used to control your body's immune response, enabling your body to accept the transplanted organ.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Olmenor Combi with food and drink

Olmenor Combi can be taken with or without food. Take the tablets with some fluid (such as one glass of water). If possible, take your daily dose at the same time each day, for example at breakfast time.
Grapefruit and grapefruit juice should not be consumed by people who are taking Olmenor Combi. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Olmenor Combi.

Elderly patients

If you are over 65 years of age, your doctor will regularly check your blood pressure at any dose increase, 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 Olmenor Combi 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 Olmenor Combi before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Olmenor Combi. Olmenor Combi 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.
If you become pregnant during therapy with Olmenor Combi, please inform and see your physician without delay.

Brest-feeding

It has been shown that amlodipine passes into breast milk in small amounts.
Tell your doctor if you are breast-feeding or about to start breast-feeding. Olmenor Combi 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.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines
You may feel sleepy, sick or dizzy, or get a headache while being treated for your high blood pressure. If this happens, do not drive or use machines until the symptoms wear off. Talk to your doctor.

3. How to take/use Olmenor Combi

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose of Olmenor Combi is one tablet per day.
- Tablets may be taken with or without food. Take the tablets with some fluid (such as one glass of water). The tablet should not be chewed. Do not take Olmenor Combi with grapefruit juice.
- If possible, take your daily dose at the same time each day, for example at breakfast time.

If you take more Olmenor Combi than you should
If you take more tablets than you should you may experience low blood pressure with symptoms such as dizziness and fast or slow heartbeat.
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 or this leaflet with you.

In case of overdose or accidental ingestion, contact your doctor or pharmacist at once, or go to the nearest hospital, indicating the medicine and the amount taken (or received).

If you forget to take Olmenor Combi
If you forget a dose, take your normal dose on the following day as usual. Do **not** take a double dose to make up for a forgotten dose.

If you stop taking Olmenor Combi
It is important to continue to take Olmenor Combi unless your doctor tells you to stop.

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

4. Possible side effects

Like all medicines, this medicine 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:

Allergic reactions that may affect the whole body, with swelling of the face, mouth and/or larynx (voice box) together with itching and skin rash may occur during treatment with Olmenor Combi. **If this happens, stop taking Olmenor Combi and contact your doctor immediately**.

Olmenor Combi can cause the blood pressure to fall too low in susceptible individuals or as the result of an allergic reaction. This could cause severe light-headedness or fainting. **If this happens stop taking Olmenor Combi, talk to your doctor immediately and lie down flat.**

Other possible side effects with Olmenor Combi:

Common (may affect up to 1 in 10 people):
Dizziness; headache; swelling of ankles, feet, legs, hands or arms; tiredness.

Uncommon (may affect up to 1 in 100 people):
Dizziness on standing up; lack of energy; tingling or numbness of hands or feet; vertigo; awareness of heartbeat; fast heartbeat; low blood pressure with symptoms such as dizziness, light-headedness; difficult breathing; cough; nausea; vomiting; indigestion; constipation; diarrhea; dry mouth; upper abdominal pain; skin rash; back pain; muscle spasms; pain in arms and legs; feeling more of an urge to pass urine; sexual inactivity; inability to get or maintain an erection; weakness.

Some changes in certain blood test results have also been seen:
Increased as well as decreased blood potassium levels, increased blood creatinine levels, increased uric acid levels, increases in a test of liver function (gamma glutamyl transferase levels).

Rare (may affect up to 1 in 1,000 people):
Fainting; drug hypersensitivity; redness and warm feeling of the face; red itchy bumps (hives); swelling of face.

Side effects reported with use of olmesartan medoxomil or amlodipine alone, but not with Olmenor Combi or in a higher frequency:

Olmesartan
Common (may affect up to 1 in 10 people):
Bronchitis; cough; sore throat; runny or stuffy nose; abdominal pain; diarrhea; indigestion; stomach flu; nausea; pain in the joints or bones; back pain; blood in the urine; infection of the urinary tract; chest pain; flu-like symptoms; pain. Changes in blood test results as increased fat levels (hypertriglyceridemia), blood urea or uric acid increased and increase in tests of liver and muscle function.

Uncommon (may affect up to 1 in 100 people):
Reduced number of a type of blood cells, known as platelets, which can result in easily bruising or prolonged bleeding time; 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); angina (pain or uncomfortable feeling in the chest known as angina pectoris); itching; skin rash; allergic skin rash; rash with hives; swelling of the face; muscular pain; feeling unwell.

Rare (may affect up to 1 in 1,000 people):
Swelling of the face, mouth and/or larynx (voice box); acute kidney failure and kidney insufficiency; lethargy.

Amlodipine
Very common (may affect more than 1 in 10 people):
Edema (fluid retention).

Common (may affect up to 1 in 10 people):
Feeling sleepy; redness and warm feeling of the face; abdominal pain; nausea; ankle swelling; visual disturbance (including double vision and blurred vision) awareness of heartbeat; diarrhea; constipation; indigestion; cramps; weakness; difficult breathing.

Uncommon (may affect up to 1 in 100 people):
Trouble sleeping; sleep disturbances; mood changes including feeling anxious; depression; irritability; tremors; taste changes; fainting; shiver ringing in the ears (tinnitus); worsening of angina pectoris (pain or uncomfortable feeling in the chest); irregular heartbeat; runny or stuffy nose; loss of hair; purplish spots or patches on the skin due to small hemorrhages (purpura); discoloration of the skin; excessive sweating; eruption of the skin; itching; red itchy bumps (hives); pain of joints or muscles; problems to pass urine; increased need to urinate (pass urine); urge to pass urine at night; breast enlargement in men; chest pain; feeling unwell; increase or decrease in weight.

Rare (may affect up to 1 in 1,000 people):
Confusion.

Very rare (may affect up to 1 in 10,000 people):
Reduction in the number of white cells in the blood, which could increase the risk of infections; a reduction in the number of a type of blood cells known as platelets, which can result in easily bruising or prolonged bleeding time; increase in blood glucose; increased tightness of muscles or increased resistance to passive movement (hypertonia); tingling or numbness of hands or feet; heart attack; inflammation of blood vessels; inflammation of stomach lining; thickening of gums; elevated liver enzymes; yellowing of the skin and eyes; increased sensitivity of the skin to light; allergic reactions; itching; rash; swelling of the face, mouth and/or larynx (voice box) together with itching and rash; severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of the mucous membranes (Stevens-Johnson's syndrome, toxic epidermal necrolysis) or other allergic reactions, sometimes life-threatening.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Olmenor Combi

Keep this medicine out of the sight and reach of children.

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

Do not store above 30 ºC.
Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Deposit containers and medicines you no longer need at the recicling containers at your pharmacy. If you are not sure, ask your pharmacist how to throw away medicines and containers you no longer need. These measures will help protect the environment.

6. Contents of the pack and other information

What Olmenor Combi contains

The active substances are:
Olmenor Combi 40 mg/5 mg: each film-coated tablet contains 40 mg of olmesartan medoxomil and 5 mg of amlodipine (as amlodipine besylate).

The other ingredients (excipients) are: pregelatinized maize starch, microcrystalline cellulose, croscarmellose, colloidal silica anhydrous, magnesium stearate, opadry II white 85F18422 (containing: poly (vinyl alcohol), titanium dioxide (E-171), macrogol 4000 and talc) and yellow iron oxide (E-172).

What Olmenor Combi looks like and contents of the pack
Olmenor Combi 40 mg/5 mg are light yellow film-coated tablets, round, biconvex and marked with 405 on one side.

Olmenor Combi film-coated tablets are available in packs of 28 tablets.

Marketing Authorization Holder and Manufacturer
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