

## **Package leaflet: Information for the user**

### **Olmenor Triple 40 mg/10 mg/25 mg film-coated tablets Olmesartan medoxomil/Amlodipine/Hydrochlorothiazide**

**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 Triple is and what it is for
2. What you need to know before you take Olmenor Triple
3. How to take Olmenor Triple
4. Possible side effects
5. How to store Olmenor Triple
6. Contents of the pack and other information

#### **1. What Olmenor Triple is and what it is used for**

This medicine contains three active substances called olmesartan medoxomil, amlodipine (as amlodipine besilate) and hydrochlorothiazide. All three substances help to control high blood pressure.

- Olmesartan medoxomil belongs to a group of medicines called “angiotensin-II receptor antagonists”, which lowers blood pressure by relaxing the blood vessels.
- Amlodipine belongs to a group of substances called “calcium channel blockers”. Amlodipine also lowers blood pressure by relaxing blood vessels.
- Hydrochlorothiazide is one of a group of medicines called thiazide diuretics. It lowers blood pressure by helping the body to get rid of extra fluid by making your kidneys produce more urine.

The actions of these substances contribute to decrease your blood pressure. Olmesartan/Amlodipine/Hydrochlorothiazide is used for the treatment of high blood pressure:

- in adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as fixed-dose combination, or
- in patients, who are already taking a fixed-dose combination of olmesartan medoxomil and hydrochlorothiazide plus the amlodipine as a single tablet or fixed-dose combination of olmesartan medoxomil and amlodipine plus hydrochlorothiazide as a single tablet.

#### **2. What you need to know before you take Olmenor Triple**

##### **Do not take Olmenor Triple**

- If you are allergic to olmesartan medoxomil, to amlodipine or a special group of calcium channel blockers (the dihydropyridines) to hydrochlorothiazide or to substances similar to hydrochlorothiazide (sulphonamides) 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 olmesartan/amlodipine/hydrochlorothiazide.
- If you have severe kidney problems.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- If you have low potassium, low sodium, high calcium, or high uric acid (with symptoms of gout or kidney stones) levels in your blood that have not got better when treated.
- If you are more than 3 months pregnant. (It is also better to avoid olmesartan/amlodipine/hydrochlorothiazide in early pregnancy - see section “Pregnancy and breast-feeding”).
- If you have severe liver problems, if bile secretion is impaired or drainage of bile from the gall bladder is blocked (e. g. by gallstones), or if you are jaundiced (yellowing of the skin and eyes).
- If you have a poor blood supply to your tissues with symptoms such as low blood pressure, low pulse, fast heartbeat, or shock (including cardiogenic shock, which means shock due to severe heart troubles).
- If you have very low blood pressure.
- the blood flow from your heart is slow or blocked. This may happen if the blood vessel or valve that takes blood away from your heart becomes narrow (aortic stenosis).
- If you have a low heart output after a heart attack (acute myocardial infarction). Low heart output may make you feel short of breath or have swelling in your feet and ankles.

Do not take olmesartan/amlodipine/hydrochlorothiazide if any of the above applies to you.

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Olmenor Triple:

- If you experience a decrease in vision or eye pain, these could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Olmesartan/Amlodipine/Hydrochlorothiazide.

**Tell your doctor** if you are taking any of the following medicines to treat high blood pressure (hypertension):

- an Angiotensin-Converting Enzyme (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 Triple”.

**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, 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 (hormone-producing glands on top of the kidneys).
- Diabetes.

- Lupus erythematosus (an autoimmune disease).
- Allergies or asthma.
- Skin reactions such as sunburn or rash after being in the sun or using a sunbed.
- If you have had skin cancer or if you have an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly its long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking this medicine.

Contact your doctor if you experience any of the following symptoms:

- Diarrhoea 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.
- Decrease in vision or eye pain These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking olmesartan/amlodipine/hydrochlorothiazide. This can lead to permanent vision impairment, if not treated.

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.

Olmesartan/amlodipine/hydrochlorothiazide 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 any of these symptoms.**

If you are due to have tests for parathyroid function, you should stop taking olmesartan/amlodipine/hydrochlorothiazide before these tests are carried out.

Sports persons are notified that this medicine contains a component that can lead to a positive doping test result.

You must tell your doctor if you think you are or might become pregnant. Olmesartan/amlodipine/hydrochlorothiazide 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)**

Olmesartan/amlodipine/hydrochlorothiazide is not recommended for children and adolescents under 18 years of age.

### **Other medicines and Olmenor Triple**

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 olmesartan/amlodipine/hydrochlorothiazide 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 Triple” and “Warnings and precautions”).
- **Lithium** (a medicine used to treat mood swings and some types of depression) used at the same time as olmesartan/amlodipine/hydrochlorothiazide may increase the toxicity of lithium. If you have to take lithium, your doctor will measure your lithium blood levels.
- **Diltiazem, verapamil**, used for heart rhythm problems and high blood pressure.
- **Rifampicin, erythromycin, clarithromycin, tetracyclines or sparfloxacin**, antibiotics used for tuberculosis and other infections.
- **St. John’s Wort** (*Hypericum perforatum*), a herbal remedy for treatment of depression.
- **Cisapride**, used to increase food movement in the stomach and gut.
- **Diphemanil**, used to treat a slow heartbeat or reduce sweating.
- **Halofantrine**, used for malaria.
- **Vincamine IV**, used to improve circulation to the nervous system.
- **Amantadine**, used for Parkinson’s disease.
- **Potassium supplements, salt substitutes containing potassium, “water tablets”** (diuretics), **heparin** (for thinning the blood and prevention of blood clots), ACE inhibitors (for blood pressure lowering), 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 acetylsalicylic acid (“aspirin”) or salicylates. Using these medicines at the same time as olmesartan/amlodipine/hydrochlorothiazide may alter the levels of potassium in your blood.
- **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 olmesartan/amlodipine/hydrochlorothiazide may increase the risk of kidney failure. The effect of olmesartan/amlodipine/hydrochlorothiazide can be decreased by NSAIDs. In case of high dosages of salicylate the toxic effect on central nervous system may be increased
- **Sleeping tablets, sedatives and anti-depressant medicines** as using these medicines together with olmesartan/amlodipine/hydrochlorothiazide may cause a sudden drop in blood pressure when standing up.
- **Colesevelam hydrochloride**, a drug that lowers the level of cholesterol in your blood, as the effect of olmesartan/amlodipine/hydrochlorothiazide may be decreased. Your doctor may advise you to take olmesartan/amlodipine/hydrochlorothiazide at least 4 hours before colesevelam hydrochloride.
- **Certain antacids** (indigestion or heartburn remedies) as the effect of olmesartan/amlodipine/hydrochlorothiazide can be slightly decreased.
- **Certain muscle relaxing medicines** such as baclofen and tubocurarine.
- **Anticholinergic agents** such as atropine and biperiden.
- **Calcium supplements.**
- **Dantrolene** (infusion for severe body temperature abnormalities).
- **Simvastatin**, used to lower levels of cholesterol and fats (triglycerides) in the blood.
- **Medicines used to control your body’s immune response** (such as tacrolimus, cyclosporine), enabling your body to accept the transplanted organ.

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

- **Treat certain mental health problems** such as thioridazine, chlorpromazine, levomepromazine, trifluoperazine, cyamemazine, sulpiride, amisulpride, pimozide, sultopride, tiapride, droperidol or haloperidol.
- **Treat low blood sugar** (e. g. diazoxide) or **high blood pressure** (e. g. betablockers, methyl dopa) as olmesartan/amlodipine/hydrochlorothiazide can affect how these drugs work.
- **Treat heart rhythm problems** such as mizolastine, pentamidine, terfenadine, dofetilide, ibutilide or erythromycin injections.
- **Treat HIV/AIDS** (e. g. ritonavir, indinavir, nelfinavir).
- **Treat fungal infections** (e. g. ketoconazole, itraconazole, amphotericin).

- **Treat heart problems** such as quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, bepridil or digitalis.
- **Treat cancers** such as amifostine, cyclophosphamide or methotrexate.
- **Increase blood pressure and slow heart rate** such as noradrenaline.
- **Treat gout** such as probenecid, sulfinpyrazone, and allopurinol.
- **Lower blood fat levels** such as colestyramine and colestipol.
- **Lower blood sugar** such as metformin or insulin.

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

### **Olmenor Triple with food and drink**

Olmesartan/amlodipine/hydrochlorothiazide can be taken with or without food.

Grapefruit and grapefruit juice should not be consumed by people who are taking olmesartan/amlodipine/hydrochlorothiazide. 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 olmesartan/amlodipine/hydrochlorothiazide.

Take care when drinking alcohol while you are taking olmesartan/amlodipine/hydrochlorothiazide, as some people feel faint or dizzy. If this happens to you, do not drink any alcohol.

### **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.

### **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 olmesartan/amlodipine/hydrochlorothiazide before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of olmesartan/amlodipine/hydrochlorothiazide. Olmesartan/amlodipine/hydrochlorothiazide 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 used after the third month of pregnancy.

If you become pregnant during therapy with olmesartan/amlodipine/hydrochlorothiazide, please inform and see your physician without delay.

#### Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Amlodipine and hydrochlorothiazide have been shown to pass into breast milk in small amounts. Olmesartan/amlodipine/hydrochlorothiazide is not recommended for mothers, who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking 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. Ask your doctor for advice.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

### 3. How to take Olmenor Triple

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 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 the tablet 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 Triple than you should**

If you take more tablets than you should 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 the event of an overdose or accidental ingestion, call your doctor or pharmacist immediately or call the toxicology information service..

#### **If you forget to take Olmenor Triple**

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 Triple**

It is important to continue to take this medicine 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 with swelling of the face, mouth and/or larynx (voice box) together with itching and rash may occur during treatment with olmesartan/amlodipine/hydrochlorothiazide. **If this happens, stop taking this medicine and contact your doctor immediately.**

Olmesartan/amlodipine/hydrochlorothiazide 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 this medicine, contact your doctor immediately and lie down flat.**

It can cause decreased vision or pain in the eyes due to high pressure [possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma].

Olmesartan/amlodipine/hydrochlorothiazide is a combination of three active substances. The following information firstly gives the other side effects reported so far with the combination olmesartan/amlodipine/hydrochlorothiazide (besides those already mentioned above) and, secondly, those side effects, which are known for each of the separate substances or when two substances are given together.

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 are the other side effects known about so far with olmesartan/amlodipine/hydrochlorothiazide:**

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

**Common** (may affect up to 1 in 10 people)

Upper respiratory tract infection; sore throat and nose; urinary tract infection; dizziness; headache; awareness of heartbeat; low blood pressure; nausea; diarrhoea; constipation; cramps; joint swelling; feeling more of an urge to pass urine; weakness; ankle swelling; tiredness; abnormal laboratory values.

**Uncommon** (may affect up to 1 in 100 people)

Dizziness on standing up; vertigo; fast heartbeat; feeling faint; redness and warm feeling of the face; cough; dry mouth; muscular weakness; inability to get or maintain an erection.

**These are the side effects, which are known for each of the separate substances or when two substances are given together:**

They may be side effects for olmesartan/amlodipine/hydrochlorothiazide, even if they have not been seen so far with this medicinal product.

**Very common** (may affect more than 1 in 10 people)

Oedema (fluid retention).

**Common** (may affect up to 1 in 10 people)

Bronchitis; stomach and gut infection; vomiting; increased blood sugar; sugar in urine; confusion; feeling sleepy; visual disturbance (including double vision and blurred vision); runny or stuffy nose; sore throat; difficult breathing; cough; abdominal pain; heartburn; stomach discomfort; flatulence; pain in the joints or bones; back pain; skeletal pain; blood in the urine; flu-like symptoms; chest pain; pain.

**Uncommon** (may affect up to 1 in 100 people)

Reduced number of a type of blood cells known as platelets, which can result in bruising easily or a prolonged bleeding time; anaphylactic reactions; abnormally reduced appetite (anorexia); problems sleeping; irritability; mood changes including feeling anxious; feeling “down” or depressed; shiver; sleep disturbances; distorted sense of taste; loss of consciousness; reduced sense of touch; tingling sensations; worsening of short-sightedness; ringing in the ears (tinnitus); angina (pain or uncomfortable feeling in the chest, known as angina pectoris); irregular heart beat; rash; loss of hair; allergic inflammation of the skin; redness of skin; purplish spots or patches on the skin due to small haemorrhages (purpura); discoloration of the skin; red itchy bumps (hives); increased sweating; itching; eruption of the skin; skin reactions to light such as sunburn or rash; muscle pain; problems to pass urine; feeling urge to pass urine at night; breast

enlargement in men; decreased sexual desire; swelling of the face; feeling unwell; weight increase or decrease; exhaustion.

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

Swollen and sore salivary glands; reduced number of white cells in the blood, which could increase the risk of infections; low red blood cell count (anaemia); bone marrow damage; restlessness; feeling uninterested (apathy); fits (convulsions); objects you look at appearing yellow; dry eyes; blood clots (thrombosis, embolism); fluid accumulation in the lungs; pneumonia; inflammation of blood vessels and small blood vessels in the skin; inflammation of the pancreas; yellowing of the skin and eyes; acute inflammation of the gall bladder; symptoms of lupus erythematosus such as rash, joint pains and cold hands and fingers; 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 mucous membranes (Stevens Johnson Syndrome, toxic epidermal necrolysis), sometimes life-threatening; impaired movement; acute kidney failure; non-infectious kidney inflammation; poor kidney function; fever.

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

High muscle tension; numbness of hands or feet; heart attack; inflammation of the stomach; thickening of the gums; blockage in the gut; inflammation of the liver.

**Not known** (frequency cannot be estimated from the available data)

Decrease in vision or eye pain (possible signs of acute angle-closure glaucoma). Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk.

Skin and lip cancer (non-melanoma skin cancer).

**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 adverse effects you can help provide more information on the safety of this medicine.

**5. How to store Olmenor Triple**

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 carton and blister after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

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

**6. Contents of the pack and other information**

**WHAT OLMENOR TRIPLE CONTAINS**



The active substances are olmesartan medoxomil, amlodipine (as amlodipine besilate) and hydrochlorothiazide.

Each film-coated tablet contains 40 mg olmesartan medoxomil, 10 mg amlodipine (as amlodipine besilate) and 25 mg hydrochlorothiazide

The other ingredients are:

*Tablet core:* pregelatinised maize starch, silicified microcrystalline cellulose, croscarmellose sodium, colloidal silica anhydrous and magnesium stearate.

*Film coat:* polyvinyl alcohol, titanium dioxide (E-171), macrogol 4000, talc, red iron oxide (E-172), and yellow iron oxide (E-172).

### **WHAT THIS PRODUCT LOOKS LIKE AND CONTENTS OF THE PACK**

Olmenor Triple 40 mg/10 mg/25 mg film-coated tablets are pink-coloured, elliptical, biconvex tablets with “OA10” debossed on one side and “H25” on the other side.

Olmenor Triple film-coated tablets is supplied in blister packs with 28 tablets.

### **MARKETING AUTHORISATION HOLDER AND MANUFACTURER**

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### **OTHER SOURCES OF INFORMATION**