

Package leaflet: Information for the user

Olmesartan medoxomil/amlodipine Teva 20 mg/5 mg Film-coated Tablets
Olmesartan medoxomil/amlodipine Teva 40 mg/5 mg Film-coated Tablets
Olmesartan medoxomil/amlodipine Teva 40 mg/10 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 on to 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 Olmesartan medoxomil/amlodipine Teva is and what it is used for
2. What you need to know before you take Olmesartan medoxomil/amlodipine Teva
3. How to take Olmesartan medoxomil/amlodipine Teva
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1. What Olmesartan medoxomil/amlodipine Teva is and what it is used for

Olmesartan medoxomil/amlodipine Teva contains two substances called olmesartan medoxomil and amlodipine (as amlodipine besilate). Both of these substances help to control high blood pressure.

- Olmesartan medoxomil 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.

Olmesartan medoxomil/amlodipine Teva is used for the treatment of high blood pressure in patients whose blood pressure is not controlled enough with either olmesartan medoxomil or amlodipine alone.

2. What you need to know before you take Olmesartan medoxomil/amlodipine Teva

Do not take Olmesartan medoxomil/amlodipine Teva:

- if you are allergic to olmesartan medoxomil or 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 Olmesartan medoxomil/amlodipine Teva.
- if you are **more than 3 months pregnant** (It is also better to avoid Invented name] in early pregnancy - see section “Pregnancy and breastfeeding”).

- 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 e.g. 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 taking Olmesartan medoxomil/amlodipine Teva.

Tell your doctor if you are taking any of the following medicines used to treat high blood pressure:

- 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 Olmesartan medoxomil/amlodipine Teva”

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).

Contact your doctor if you experience 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.

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 that you are (or might become) pregnant. Olmesartan medoxomil/amlodipine Teva 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

Olmesartan medoxomil/amlodipine Teva is not recommended for children and adolescents under the age of 18.

Other medicines and Olmesartan medoxomil/amlodipine Teva

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 medoxomil/amlodipine Teva 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 Olmesartan medoxomil/amlodipine Teva” 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 Olmesartan medoxomil/amlodipine Teva 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 Olmesartan medoxomil/amlodipine Teva 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 Olmesartan medoxomil/amlodipine Teva may increase the risk of kidney failure. The effect of Olmesartan medoxomil/amlodipine Teva can be decreased by NSAIDs.
- **Colesevelam hydrochloride**, a drug that lowers the level of cholesterol in your blood, as the effect of [Invented name] may be decreased. Your doctor may advise you to take Olmesartan medoxomil/amlodipine Teva at least 4 hours before colesevelam hydrochloride.
- **Certain antacids** (indigestion or heartburn remedies), as the effect of Olmesartan medoxomil/amlodipine Teva 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** (agents used for tuberculosis or other infections).
- **St. John’s wort** (*Hypericum perforatum*), a herbal remedy.
- **Dantrolene** (infusion for severe body temperature abnormalities).
- **Simvastatin**, 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.

Olmesartan medoxomil/amlodipine Teva with food and drink

Olmesartan medoxomil/amlodipine Teva can be taken with or without food. Swallow the tablet 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 (see section 3).

Grapefruit juice and grapefruit must not be consumed by people who are taking Olmesartan medoxomil/amlodipine Teva.

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 medoxomil/amlodipine Teva.

Elderly

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 Olmesartan medoxomil/amlodipine Teva can be somewhat less in black patients.

Pregnancy and breast-feeding

Pregnancy: You must tell your doctor if you think that you are (or **might become**) pregnant. Your doctor will normally advise you to stop taking Olmesartan medoxomil/amlodipine Teva before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Olmesartan medoxomil/amlodipine Teva. Olmesartan medoxomil/amlodipine Teva 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 Olmesartan medoxomil/amlodipine Teva, please inform and see your physician without delay.

Breast-feeding: Tell your doctor if you are breast-feeding or about to start breast-feeding. Olmesartan medoxomil/amlodipine Teva 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 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.

<Olmesartan medoxomil/amlodipine Teva contains lactose

If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicinal product.

3. How to take Olmesartan medoxomil/amlodipine Teva

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 Olmesartan medoxomil/amlodipine Teva is one tablet per day.
- The tablets can be taken with or without food. Swallow the tablet with some fluid (such as a glass of water). The tablet should not be chewed. Do **not** take them with grapefruit juice.
- If possible, take your daily dose at the same time each day, for example at breakfast time.

Olmesartan medoxomil/amlodipine Teva 20mg/5mg and 40mg/5mg film-coated tablets: The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Olmesartan medoxomil/amlodipine Teva 40mg/10mg film-coated tablets: The tablet can be divided into equal doses. Hence, the 20mg/5 mg dose can be obtained by breaking the 40mg/10mg tablet in equal doses and taking half a tablet per day.

If you take more Olmesartan medoxomil/amlodipine Teva than you should

If you take more tablets than you should you may experience low blood pressure with symptoms such as dizziness, fast or slow heart beat.

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.

If you forget to take Olmesartan medoxomil/amlodipine Teva

If you forget to take 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 Olmesartan medoxomil/amlodipine Teva

It is important to continue to take Olmesartan medoxomil/amlodipine Teva 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 rash may occur during treatment with Olmesartan medoxomil/amlodipine Teva. **If this happens stop taking Olmesartan medoxomil/amlodipine Teva and talk to your doctor immediately.**

Olmesartan medoxomil/amlodipine Teva 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 Olmesartan medoxomil/amlodipine Teva, talk to your doctor immediately and lie down flat.**

Other possible side effects with Olmesartan medoxomil/amlodipine Teva:

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 heart beat; fast heart beat; low blood pressure with symptoms such as dizziness, light-headedness; difficult breathing; cough; nausea; vomiting; indigestion; diarrhoea; constipation; dry mouth, upper abdominal pain; skin rash; cramps; pain in arms and legs; back pain; feeling more of an urge to pass urine; sexual inactivity; inability to get or maintain an erection; weakness.

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

Drug hypersensitivity; fainting; 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 Olmesartan medoxomil/amlodipine Teva or in a higher frequency:

Olmesartan medoxomil

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

Bronchitis; sore throat; runny or stuffy nose; cough; abdominal pain; stomach flu; diarrhoea; indigestion; 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 (hypertriglyceridaemia), 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; eruption of the skin; 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):

Oedema (fluid retention)

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

Abdominal pain; nausea; ankle swelling; feeling sleepy; redness and warm feeling of the face, visual disturbance (including double vision and blurred vision), awareness of heartbeat, diarrhoea, 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; shiver; taste changes; fainting; 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 haemorrhages (purpura); discoloration of the skin; excessive sweating; eruption of the skin; itching; red itchy bumps (hive); pain of joints or muscles; problems to pass urine; urge to pass urine at night; increased need to urinate (pass urine); breast enlargement in men; chest pain; 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 the liver or the pancreas; 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 mucous membranes, sometimes life-threatening.

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

The following side effects have also been reported by patients taking Olmesartan medoxomil/amlodipine Teva: disorders combining rigidity, tremor, and/or movements disorders, trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Olmesartan medoxomil/amlodipine Teva

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, the bottle and the blister. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Olmesartan medoxomil/amlodipine Teva contains

- The active substances are olmesartan medoxomil and amlodipine (as besilate).
Each tablet contains 20 mg of olmesartan medoxomil and 5 mg amlodipine (as besilate).
Each tablet contains 40 mg of olmesartan medoxomil and 5 mg amlodipine (as besilate).
Each tablet contains 40 mg of olmesartan medoxomil and 10 mg amlodipine (as besilate).

The other ingredients are cellulose microcrystalline, lactose monohydrate, crospovidone, povidone, sodium starch glycolate (potato), silica, colloidal hydrated, magnesium stearate.

The other ingredients in the film-coating are polyvinyl alcohol part-hydrolyzed (E1203), macrogol (E1521, polyethylene glycol), talc (E553b), iron oxide red (E172) (Olmesartan medoxomil/amlodipine Teva 40mg/10mg film-coated tablets only), titanium dioxide (E171) (Olmesartan medoxomil/amlodipine Teva 20mg/5mg, 40mg/5mg film-coated tablets only), iron oxide yellow (E172) (Olmesartan medoxomil/amlodipine Teva 40/5mg film-coated tablets only).

What Olmesartan medoxomil/amlodipine Teva looks like and contents of the pack

Olmesartan medoxomil/amlodipine Teva 20 mg/5 mg film-coated tablets are white, round standard convex, film coated tablets, debossed with "5" on one side, the other side of the tablet is scored and debossed with "2" on the left side of the score and "0" on the right side.

Olmesartan medoxomil/amlodipine Teva 40 mg/5 mg film-coated tablets are yellowish, round standard convex, film coated tablets, debossed with "5" on one side, the other side of the tablet is scored and debossed with "4" on the left side of the score and "0" on the right side.

Olmesartan medoxomil/amlodipine Teva 40 mg/10 mg film-coated tablets are brownish red, round standard convex, film coated tablets, debossed with "10" on one side, the other side of the tablet is scored and debossed with "4" on the left side of the score and "0" on the right side.

The following pack sizes are available:

OPA/Alu/PE+ desiccant – Aluminium blister packs

Blister 20/5mg: Pack size of 14, 28, 28(28x1), 30, 30(30x1), 56, 90, 98,120 film-coated tablets

Blister 40/5mg: Pack size of 28, 28(28x1), 30, 30(30x1), 56, 90, 98,120 film-coated tablets

Blister 40/10mg: Pack size of 28, 28(28x1), 30, 30(30x1), 56, 90, 98,120 film-coated tablets

Bottle

100 film-coated tablets in a HDPE bottle. Each bottle contains a canister with a desiccant for keeping the tablets dry.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturer

Merckle GmbH
Ludwig-Merckle-Strasse 3, Blaubeuren
Baden-Wuerttemberg
Germany.

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Olmesartan/Amlodipine Teva filmomhulde tabletten
Bulgaria	Олместа А филмирани таблетки.
Germany	Olmesartan/Amlodipin AbZ Filmtabletten
Estonia	Olmesartan medoxomil/Amlodipine Teva
Spain	Olmesartan/Amlodipino Teva comprimidos recubiertos conpelícula EFG
Ireland	Olmesartan medoxomil/amlodipine Teva Film-coated Tablets
Italy	Olmesartan medoxomil e Amlodipina Teva
Lithuania	Olmesartan medoxomil/Amlodipine Teva plėvele dengtos tabletės
Latvia	Olmesartan medoxomil/Amlodipine Teva apvalkotās tabletes
The Netherlands	Olmesartan medoxomil/Amlodipine Teva filmomhulde tabletten
Portugal	Olmesartan medoxomilo + Amlodipina Teva

This leaflet was last revised in October 2017