Package leaflet: information for the patient

Olmesartan Krka 10 mg film-coated tablets
Olmesartan Krka 20 mg film-coated tablets
Olmesartan Krka 40 mg film-coated tablets
olmesartan medoxomil

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 Krka is and what it is used for

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

Olmesartan Krka is used for the treatment of high blood pressure (also known as 'hypertension') in adults and children and adolescents aged 6 to less than 18 years. 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 Olmesartan Krka 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. What you need to know before you take Olmesartan Krka

Do not take Olmesartan Krka
- if you are allergic to olmesartan medoxomil or any of the other ingredients of this medicine (listed in section 6).
- if you are more than 3 months pregnant (it is also better to avoid Olmesartan Krka 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).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions

Talk to your doctor or pharmacist before taking Olmesartan Krka.

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 Krka"

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

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 you are (or might become) pregnant. Olmesartan Krka 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).

Children and adolescents
Olmesartan Krka has been studied in children and adolescents. For more information, talk to your doctor. Olmesartan Krka is not recommended for children from 1 year to less than 6 years and should not be used in children under the age of 1 year as no experience is available.

Other medicines and Olmesartan Krka
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:
- Other blood pressure lowering medicines, as the effect of Olmesartan Krka 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 Krka" and "Warnings and precautions")
- 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 Olmesartan Krka 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 Krka 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 Olmesartan Krka may increase the risk of kidney failure and the effect of Olmesartan Krka can be decreased by NSAIDs.
- Colesevelam hydrochloride, a drug that lowers the level of cholesterol in your blood, as the

effect of Olmesartan Krka may be decreased. Your doctor may advise you to take Olmesartan Krka at least 4 hours before.
- Certain antacids (indigestion remedies), as the effect of Olmesartan Krka can be slightly decreased.

Older people
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 Olmesartan Krka is somewhat less in black patients.

Olmesartan Krka with food and drink
Olmesartan Krka can be taken with or without food.

Pregnancy and breast-feeding
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.

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

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Olmesartan Krka 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.

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.

Olmesartan Krka contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Olmesartan Krka

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

Adults
The recommended 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.

Children and adolescents from 6 to less than18 years of age

The recommended starting dose is 10 mg once daily. If the patient's blood pressure is not adequately controlled, the doctor may decide to change the dose up to 20 or 40 mg once a day. In children who weigh less than 35 kg, the dose will not be higher than 20 mg once a day.

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

The tablets can be taken with or without food. Swallow the tablets with a sufficient amount of water (e.g. one glass). If possible, take your daily dose at the same time each day, for example at breakfast time.

If you take more Olmesartan Krka 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 Olmesartan Krka
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 Olmesartan Krka
It is important to continue to take Olmesartan Krka 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 side effects can be serious:

On rare occasions (may affect up to 1 in 1,000 people) the following allergic reactions, that may affect the whole body have been reported:
Swelling of the face, mouth and/or larynx (voice box) together with itching and rash may occur during treatment with Olmesartan Krka. **If this happens stop taking Olmesartan Krka and contact your doctor immediately.**

Rarely (but slightly more often in older people) Olmesartan Krka 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 occurs stop taking Olmesartan Krka, contact your doctor immediately and lie down flat.**

Frequency not known: If you experience yellowing of the whites of the eyes, dark urine, itching of the skin, even if you started therapy with Olmesartan Krka longer time ago, **contact your doctor immediately** who will evaluate your symptoms and decide on how to continue your blood pressure medication.

These are the other side effects known about so far with Olmesartan Krka:

<u>Common side effects (may affect up to 1 in 10 people):</u>
Dizziness, headache, nausea, indigestion, diarrhoea, stomach ache, gastroenteritis, tiredness, sore throat, runny or stuffy nose, bronchitis, flu-like symptoms, cough, pain, 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), rise in blood

urea, increases in tests of liver and muscle function.

Uncommon side effects (may affect up to 1 in 100 people):
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), vertigo, vomiting, weakness, feeling unwell, muscular pain, skin rash, allergic skin rash, itching, exanthema (skin eruption), skin lumps (wheals), angina (pain or uncomfortable feeling in the chest).

In blood tests a reduction of the numbers of a type of blood cell, known as platelets has been seen (thrombocytopenia).

Rare side effects (may affect up to 1 in 1,000 people):
Lack of energy, muscle cramps, impaired kidney function, kidney failure.

Some changes in blood test results have also been seen. These include increased potassium levels (hyperkalaemia) and increased levels of compounds related to kidney function.

Children and adolescents
In children, side effects are similar to those reported in adults. However, dizziness and headache are seen more often in children, and nose bleeding is a common side effect seen in children only.

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. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Olmesartan Krka

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 packaging after EXP. 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 Krka contains
- The active substance is olmesartan medoxomil.
  Each Olmesartan Krka 10 mg film-coated tablet contains 10 mg olmesartan medoxomil.
  Each Olmesartan Krka 20 mg film-coated tablet contains 20 mg olmesartan medoxomil.
  Each Olmesartan Krka 40 mg film-coated tablet contains 40 mg olmesartan medoxomil.
- The other ingredients are cellulose microcrystalline, lactose monohydrate, low-substituted hydroxypropylcellulose and magnesium stearate in the tablet core and, titanium dioxide, talc, macrogol 3000 and poly(vinyl alcohol) in the film coating.
  See section 2 "Olmesartan Krka contains lactose".

What Olmesartan Krka looks like and contents of the pack
Film-coated tablets of 10 mg are white, round, slightly biconvex film-coated tablets, engraved with a mark S1 on one side of the tablet; tablet diameter: 6.5 mm, thickness 2.4 mm – 3.4 mm.

Film-coated tablets of 20 mg are white, round, slightly biconvex film-coated tablets, engraved with a mark S2 on one side of the tablet; tablet diameter: 8 mm, thickness 3.4 mm – 4.5 mm.
Film-coated tablets of 40 mg are white, oval, biconvex film-coated tablets, engraved with a mark S3 on one side of the tablet; tablet dimensions: 13x8 mm, thickness 4.3 mm – 5.5 mm.

Olmesartan Krka 10 mg, 20 mg and 40 mg film-coated tablets are available in boxes of 10, 14, 28, 30, 56, 60, 84, 90, 98 and 100 film-coated tablets in blisters and in tablet containers of 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5**,** 27472 Cuxhaven**,** Germany

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria, Belgium, Spain, Ireland	Olmesartan Krka
Cyprus	Olmesartan TAD
Greece	Olelom
Germany	Olmecor
Denmark, Finland, Netherlands, Norway	Olmesartan medoxomil Krka
Croatia	Olimestra
Italy	Olmesartan HCS
Portugal	Olmesartan medoxomilo Krka
United Kingdom (Northern Ireland)	Olmesartan

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