Package leaflet: Information for the patient

Olmesartan/Hydrochlorothiazide Krka 20 mg/12.5 mg film-coated tablets
Olmesartan/Hydrochlorothiazide Krka 20 mg/25 mg film-coated tablets
olmesartan medoxomil/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 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/Hydrochlorothiazide Krka is and what it is used for

Olmesartan/Hydrochlorothiazide Krka contains two active substances, olmesartan medoxomil and hydrochlorothiazide that are used to treat high blood pressure (hypertension) in adult patients:

- 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 Olmesartan/Hydrochlorothiazide Krka if olmesartan medoxomil alone has not adequately controlled your blood pressure. When given together, the two active substances in Olmesartan/Hydrochlorothiazide Krka 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 Olmesartan/Hydrochlorothiazide Krka to lower it more.

High blood pressure can be controlled with medicines such as Olmesartan/Hydrochlorothiazide 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/Hydrochlorothiazide Krka

Do not take Olmesartan/Hydrochlorothiazide Krka
- if you are allergic to olmesartan medoxomil or hydrochlorthiazide, or any of the other

ingredients of this medicine (listed in section 6) or substances similar to hydrochlorothiazide (sulfonamides)
- if you are more than 3 months pregnant (it is also better to avoid Olmesartan/Hydrochlorothiazide Krka in early pregnancy – see pregnancy section)
- if you have severe kidney problems
- if you 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
- if you 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 have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren

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.

Warnings and precautions
Talk to your doctor or pharmacist before using Olmesartan/Hydrochlorothiazide Krka
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
- If you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly 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 using Olmesartan/Hydrochlorothiazide Krka
- If you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Olmesartan/Hydrochlorothiazide Krka, seek medical attention immediately.
- 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/Hydrochlorothiazide Krka. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this
- 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/Hydrochlorothiazide Krka”

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

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.

Olmesartan/Hydrochlorothiazide Krka 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.

Olmesartan/Hydrochlorothiazide Krka 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 water, 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 Olmesartan/Hydrochlorothiazide Krka 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. Olmesartan/Hydrochlorothiazide 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/Hydrochlorothiazide Krka is not recommended for children and adolescents under the age of 18.

Other medicines and Olmesartan/Hydrochlorothiazide Krka
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 Olmesartan/Hydrochlorothiazide Krka. 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

- 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/Hydrochlorothiazide Krka" and "Warnings and precautions")

- Lithium (a medicine used to treat mood swings and some types of depression) used at the same time as Olmesartan/Hydrochlorothiazide 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/Hydrochlorothiazide Krka may increase the risk of kidney failure and the effect of

Olmesartan/Hydrochlorothiazide Krka can be decreased by NSAIDs

- Other blood pressure lowering medicines (anti-hypertensives), as the effect of Olmesartan/Hydrochlorothiazide Krka can be increased

- Sleeping tablets, sedatives and anti-depressant medicines, as using these medicines together with Olmesartan/Hydrochlorothiazide Krka 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

Colesevelam hydrochloride, a drug that lowers the level of cholesterol in your blood, as the effect of Olmesartan/Hydrochlorothiazide Krka may be decreased. Your doctor may advise you to take Olmesartan/Hydrochlorothiazide Krka at least 4 hours before colesevelam hydrochloride.

- Anticholinergic agents, such as atropine and biperiden

- Drugs such as thioridazine, chlorpromazine, levomepromazine, trifluoperazine, cyamemazine, sulpiride, amisulpride, pimozide, 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, a medicine used to treat high blood pressure and low blood sugar, respectively, as **Olmesartan/Hydrochlorothiazide Krka** can enhance their blood-sugar-increasing effect.

- Methyldopa, 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, sulfinpyrazone and allopurinol, used to treat gout

- Calcium supplements

- Amantadine, an anti-viral drug

- Cyclosporin, a medicine used to stop rejection of organ transplants

- Certain antibiotics called tetracyclines or sparfloxacin

- 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 Olmesartan/Hydrochlorothiazide Krka can be slightly decreased.

- Cisapride, used to increase food movement in the stomach and gut

- Halofantrine, used for malaria.

Olmesartan/Hydrochlorothiazide Krka with food, drink and alcohol
Olmesartan/Hydrochlorothiazide Krka can be taken with or without food.

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

Black patients
As with other similar drugs the blood pressure lowering effect of Olmesartan/Hydrochlorothiazide Krka is 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/Hydrochlorothiazide 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/Hydrochlorothiazide Krka. Olmesartan/Hydrochlorothiazide Krka 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.

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

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 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.

3. How to take Olmesartan/Hydrochlorothiazide Krka

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

The recommended dose of Olmesartan/Hydrochlorothiazide Krka 20 mg/12.5 mg is one tablet a day. However, if your blood pressure is not controlled, your doctor may decide to change your dose to one Olmesartan/Hydrochlorothiazide Krka 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 Olmesartan/Hydrochlorothiazide Krka until your doctor tells you to stop.

If you take more Olmesartan/Hydrochlorothiazide Krka 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 Olmesartan/Hydrochlorothiazide Krka
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/Hydrochlorothiazide Krka
It is important to continue to take Olmesartan/Hydrochlorothiazide 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.

However, the following 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 Olmesartan/Hydrochlorothiazide Krka and contact your doctor immediately.**

- **Olmesartan/Hydrochlorothiazide Krka** 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 Olmesartan/Hydrochlorothiazide 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/Hydrochlorothiazide Krka longer time ago, **contact your doctor immediately** who will evaluate your symptoms and decide on how to continue your blood pressure medication.

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

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

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

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

Uncommon side effects (may affect up to 1 in 100 people):
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 (may affect up to 1 in 1,000 people):

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 Olmesartan/Hydrochlorothiazide Krka or in a higher frequency:

Olmesartan medoxomil:

Common side effects (may affect up to 1 in 10 people):
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 (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), 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 (may affect up to 1 in 1,000 people):
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 (may affect more than 1 in 10 people):
Changes in blood results including: Increase in blood fat and uric acid levels.

Common side effects (may affect up to 1 in 10 people):
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 (may affect up to 1 in 100 people):
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 (may affect up to 1 in 1,000 people):
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 uninterested (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 (may affect up to 1 in 10,000 people):
Electrolyte disturbance leading to an abnormally depleted level of chloride in the blood (hypochloraemic alkalosis), blockage in the gut (paralytic ileus), acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).

Not known (frequency cannot be estimated from the available data)
Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma), 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. 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/Hydrochlorothiazide 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.

Store in the original package in order to protect from moisture.

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/Hydrochlorothiazide Krka contains
- The active substances are olmesartan medoxomil and hydrochlorothiazide.
  Olmesartan/Hydrochlorothiazide Krka 20 mg/12.5 mg film-coated tablets
  Each film-coated tablet contains 20 mg olmesartan medoxomil and 12.5 mg hydrochlorothiazide.
  Olmesartan/Hydrochlorothiazide Krka 20 mg/25 mg film-coated tablets
  Each film-coated tablet contains 20 mg olmesartan medoxomil and 25 mg hydrochlorothiazide.

- The other ingredients are microcrystalline cellulose, magnesium stearate and low-substituted hydroxypropylcellulose in the tablet core and titanium dioxide, talc, poly(vinyl alcohol) and macrogol 3000 in the film coating.

What Olmesartan/Hydrochlorothiazide Krka looks like and contents of the pack

Olmesartan/Hydrochlorothiazide Krka 20 mg/12.5 mg film-coated tablets are white to almost white, round, biconvex, engraved with a mark C1 on one side of the tablet, diameter 9 mm.
Olmesartan/Hydrochlorothiazide Krka 20 mg/25 mg film-coated tablets are white to almost white,

oval, biconvex, engraved with a mark C2 on one side of the tablet, dimensions 12 mm x 6 mm.

Film-coated tablets are available in boxes of 10, 14, 28, 30, 56, 60, 84, 90, 98 and 100 film-coated tablets.

Not all pack sizes may be marketed.

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

This medicine is authorised in the Member States of the European Economic Area under the following names:

Name of the Member State	**Name of the medicine**
Austria	Olmesartan/HCT Krka
Belgium	Olmesartan/HCTZ Krka
Cyprus	Olmesartan/Hydrochlorothiazide TAD
Germany	Olmecor HCT
Greece	Olelom HCT
Denmark	Olmesartan medoxomil/hydrochlorothiazide Krka
Spain	Olmesartan/Hidrochlorotiazida Krka
Finland	Olmesartan medoxomil/Hydrochlorothiazide Krka
Croatia	Co-Olimestra
Ireland	Olmesartan/Hydrochlorothiazide Krka
Italy	Olmesartan medoxomil e Idroclorotiazide HCS
Netherlands	Olmesartan medoxomil/Hydrochloortiazide Krka
Norway	Olmesartan medoxomil/Hydrochlorothiazide Krka
Portugal	Olmesartan medoxomilo + Hidroclorotiazida Krka

This leaflet was last revised in