Package leaflet: Information for the user

Naproxen sodium Krka 550 mg

film-coated tablets

Naproxen sodium

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 any side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Naproxen sodium Krka is and what it is used for

Naproxen sodium Krka contains as active substance naproxen sodium, a substance belonging to the group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs).

Naproxen sodium Krka is used for:
- treatment of mild to moderate pain,
- symptomatic treatment of rheumatoid arthritis (inflammation of the joints, usually including those of hands and feet, resulting in swelling and pain), osteoarthritis (chronic disorder causing cartilage damage), acute gout attacks and ankylosing spondylitis (inflammation that affects the joints of the spine),
- relief of menstrual pain,
- relief of pain from acute migraine headaches,
- treatment of pain due to bleeding associated with an insertion of intrauterine device (IUD).

2. What you need to know before you take Naproxen sodium Krka

Do not take Naproxen sodium Krka
- if you are allergic to naproxen sodium or any of the other ingredients of this medicine (listed in section 6);
- if you have experienced difficulty breathing (bronchial asthma), hives (urticaria) or inflammation of the mucous membrane of the nose (rhinitis) when taking acetylsalicylic acid and other nonsteroidal anti-inflammatory drugs (NSAID, nonsteroidal antirheumatics);
- if you are currently suffering from or have suffered in more than one occasion from: an ulcer or bleeding from the stomach or duodenum;
- if you have experienced gastrointestinal bleeding or perforation when taking NSAIDs;
- if you suffer from severe heart failure;
- if you are during the third trimester of pregnancy;
- if you suffer from ulcerative colitis (an intestinal disease);
- if you suffer from severe liver impairment (alterations in the liver) or kidney impairment (alterations in the kidney);
- if you are taking other medicines of this type (nonsteroidal anti-inflammatory drugs).

Warnings and precautions

Talk to your doctor or pharmacist before taking Naproxen sodium Krka.
- It is important that you use the lowest effective dose for the shortest duration necessary to control symptoms
- If you have had or develop an ulcer, bleeding or perforation in the stomach or duodenum, which may be manifested by severe or persistent abdominal pain and/ or by faeces of black colour, or even without previous warning symptoms.
- If you have previously had stomach or duodenal bleeding or have had a perforation of the digestive system while taking a nonsteroidal anti-inflammatory drug.
- This risk is increased when high doses and prolonged treatments are used in patients with a history of peptic ulcer and in the elderly. In these cases your doctor will consider the possibility of associating stomach protective agents.
- If you have or have had stomach problems, since Naproxen sodium Krka may cause stomach irritation, bleeding or ulcers. Your doctor will recommend you the most appropriate dose.
- If you suffer from Crohn's disease or ulcerative colitis, as Naproxen sodium Krka medicines may worsen these conditions.
- If you have asthma or allergic disorders (such as rhinitis or nasal polyps), as Naproxen sodium Krka may cause difficulties in breathing (bronchospasm).
- If you have severe kidney, liver or heart problems.
- If you are simultaneously taking medicines that alter blood clotting or increase the risk of ulcers, such as oral anticoagulants or acetylsalicylic-acid-type antiplatelet agents. You should also talk to your doctor about the use of other medicines that may increase the risk of such bleeds such as corticosteroids and selective serotonin reuptake inhibitor antidepressants.
- If you have or think you may have an infection, since Naproxen sodium Krka may hide the usual signs and symptoms of infectious processes.
- If you while taking Naproxen sodium Krka feel stomach pains and/or see that your faeces appear with black coloration, you should stop taking Naproxen sodium Krka.
- If you suffer from vision disorders during treatment.
- This medicine should be used with caution in patients who have a low-salt diet and a history of digestive problems.

Naproxen sodium Krka may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems to become pregnant.

Medicines such as Naproxen sodium Krka may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, a history of stroke, or think you may be at risk for these conditions (for example, high blood pressure, diabetes, high cholesterol, or you are a smoker) you should ask your doctor or pharmacist before using this medicine.

In addition, this type of medicines may produce fluid retention, especially in patients with heart failure and/or high blood pressure (hypertension).

Other medicines and Naproxen sodium Krka

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

As a result of interaction with some other medicines, the effect of either Naproxen sodium Krka or these medicines may be increased or decreased. This occurs with:
- medicines used to neutralizes stomach acidity (antacids or cholestyramine)
- medicines used to prevent the clotting of blood (warfarin),
- medicines used to prevent blood clots (Aspirin/ acetylsalicylic acid),
- medicines used to treat diabetes (sulphonylurea),
- medicines used to treat epilepsy (hydantoin derivatives),
- medicines used to treat high blood pressure (angiotensin receptor antagonists or blockers and diuretics)
- medicines that increase urination (furosemide),
- medicines used to treat mental disorders (lithium),
- medicines used to treat malignant diseases (methotrexate),
- medicines used to treat joint pain and inflammation (steroids and corticosteroids).

Naproxen sodium Krka with food and drink

Take the tablets with sufficient amount of liquid and preferably with food.

Pregnancy, breast-feeding and fertility

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.

Naproxen sodium Krka should not be administered during pregnancy, childbirth, or breast-feeding.

Because administration of naproxen-type drugs has been associated with an increased risk of congenital anomalies, administration of the drug during the first and second trimesters of pregnancy is not recommended unless strictly necessary. In these cases the dosage and duration should be limited to the minimum possible.

In the third trimester the administration of Naproxen sodium Krka is contraindicated.

Women of childbearing age should take into account that naproxen-type drugs have been associated with a decreased ability to conceive.

Driving and using machines

Naproxen sodium Krka should be used with caution in patients whose activity requires attention and who have observed vertigo or visual disturbances during treatment with this drug.

Naproxen sodium Krka contains sodium

This medicinal product contains 2.17 mmol (or 50.00 mg) sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

3. How to take Naproxen sodium 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 and children over 16 years of age

Daily dose is usually 1 or 2 tablets (550 mg or 1100 mg naproxen sodium). The recommended initial dose is 1 tablet (550 mg naproxen sodium) followed by half a tablet (275 mg naproxen sodium) every 6 or 8 hours, depending on the intensity of the condition. Your doctor may modify this dosage.

Rheumatoid arthritis, osteoarthritis, ankylosing spondylitis:
The recommended initial dose is 550 mg of naproxen sodium (1 tablet) twice daily (morning and evening) or 1100 mg of naproxen sodium (2 tablets) taken once a day.

Acute gout
The recommended initial dose is 825 mg of naproxen sodium (1 and a half tablets), followed by 275 mg of naproxen sodium (half a tablet) every 8 hours until the attack diminish.

Dysmenorrhoea (menstrual pain)
The recommended initial dose is 550 mg of naproxen sodium (1 tablet), followed by 275 mg of naproxen sodium (half a tablet) every 6-8 hours if necessary.

Migraine headaches
The recommended initial dose is 825 mg of naproxen sodium (1 and a half tablets) when the first symptoms appear, followed by 275 mg of naproxen sodium (half a tablet) half hour later.

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Menorrhagia (pain associated with excessive menstrual bleeding)
The recommended first day daily dose is between 825 mg (1and a half tablets) and 1375 mg of naproxen sodium (2 and a half tablets) divided into two doses, followed by a daily dose between 550 mg (1 tablet) and1100 mg of naproxen sodium (2 tablets) divided into two doses, for a maximum period of four days.

Children and adolescents under 16 years of age
Naproxen sodium Krka is not intended to be used in children and adolescents under 16 years of age.

Elderly
The dose should be reduced in elderly patients and the lowest effective dose should be used for the shortest possible duration. Talk to your doctor or pharmacist.

Patients with renal and/or hepatic insufficiency
If you have renal and/or hepatic insufficiency the dose should be reduced and the lowest effective dose should be used for the shortest possible duration. Talk to your doctor or pharmacist.

Method of administration
This medicine is for oral use.
The tablet can be divided into equal doses.
Swallow your tablets with a drink of water and preferably with food.
Always take the lowest effective dose.

If you take more Naproxen sodium Krka than you should
If you have taken more Naproxen sodium Krka than you should, ask your doctor or pharmacist immediately.
Overdose symptoms are characterized by drowsiness, heartburn, indigestion, nausea, vomiting and, in some cases, seizures. In case of an accidental or voluntary overdose, gastric lavage should be performed and symptomatic treatment should be established. Rapid administration of 50-100 g activated charcoal as aqueous suspension reduces the absorption of the drug.

If you forget to take Naproxen sodium Krka
Do not take a double dose to make up for a forgotten tablet. Take the medicine at about the same time each day. If you forget to take the medicine at the scheduled time, take it as soon as you remember.

If you stop taking Naproxen sodium Krka
If you take naproxen sodium for short-term pain relief, you may safely stop taking it as soon as you no longer need it. When long-term treatment is prescribed, you should consult with your doctor before stopping treatment.

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.

Adverse effects that may occur during the treatment with this drug, with a very rare frequency (may affect up to 1 in 10,000 people):

Gastrointestinal disorders: The most common side effects observed with naproxen sodium are gastrointestinal in nature (affecting the stomach and intestine). Inflammation, bleeding (in some cases fatal, especially in the elderly), peptic ulcers, perforation and obstruction of the upper or lower gastrointestinal tract (digestive tract) may occur. There have been cases of esophagitis (inflammation of the oesophagus), gastritis (inflammation of the stomach lining), pancreatitis (inflammation of the pancreas), stomatitis (inflammation of the oral mucosa) and worsening of ulcerative colitis and Crohn's disease. There have also been cases of stomach acidity, dyspepsia (digestion disorders), abdominal discomfort, nausea, vomiting, diarrhoea, constipation, flatulence (gas), haematemesis (vomiting blood) and melena (blackish stools).

Blood and lymphatic system disorders: agranulocytosis (increase/decrease in certain white blood cells), aplastic and haemolytic anaemia (reduced number of red cells, white cells and platelets in blood), eosinophilia (increase of certain white blood cells in blood), leucopoenia (decreased number of leucocytes in blood), thrombocytopenia (decreased platelet count).

Immune system disorders: anaphylactic reactions (severe allergic reaction), angioneurotic oedema (swelling of the skin, mucosa and viscera).

Metabolism and nutrition disorders: hypercalcaemia (increased concentration of calcium in blood).

Psychiatric disorders: difficulty concentrating, depression, sleep disturbances.

Nervous system disorders: dizziness, drowsiness, headache, dizziness, vertigo, cognitive dysfunction, aseptic meningitis (inflammation of the meninges), seizures, insomnia.

Eye disorders: visual disturbances, corneal opacity, optic papillitis (inflammation of the papilla), retrobulbar neuritis (inflammation of the optic nerve) and papilloedema.

Ear and labyrinth disorders: hearing disturbances, tinnitus (buzzing in the ears), hearing loss (decreased hearing).

Cardiac disorders: palpitations, congestive heart failure (inability of the heart to perform its pumping function), hypertension (high blood pressure). Medicines like naproxen sodium may be associated with a moderate increased risk of a heart attack ("myocardial infarction") or stroke.

Vascular disorders: vasculitis (inflammation of blood vessels), oedema.

Respiratory, thoracic and mediastinal disorders: asthma, eosinophilic pneumonitis, dyspnoea (shortness of breath), pulmonary oedema.

Infections and infestations: aseptic meningitis.

Hepatobiliary disorders: hepatitis (liver inflammation), jaundice (yellowing of the skin) .

Skin and subcutaneous tissue disorders: skin bleeding, itching, capillary bleeding, rashes, sweating, hair loss, skin peeling, lichen planus (skin disease consisting of small nodules planes), reaction consisting of pus vesicles, redness of the skin, systemic lupus erythematosus (autoimmune disease with typical skin signs, rash and redness of the skin), very severe blistering reactions such as Stevens-Johnson syndrome (map-looking skin rash) and toxic epidermal necrolysis, allergy, photosensitivity reactions including rare cases in which the skin takes an aspect of porphyria cutanea tarda, pseudoporphyria (defective liver enzymes) or epidermolysis bullosa. If skin fragility, blistering or other symptoms indicative of pseudoporphyria occur, treatment and monitoring of the patient should be discontinued.

Musculoskeletal and connective tissue disorders: muscular pain, muscular fatigue.

Renal and urinary disorders: blood in the urine, interstitial nephritis (kidney inflammation with brownish-yellowish discoloration), nephritic syndrome, renal disease, renal impairment, renal papillary necrosis (death of cells forming kidney papillae as a consequence of metabolism alteration).

Reproductive system and breast disorders: infertility.

General disorders and administration site conditions: malaise, pyrexia (chills and fever), thirst, sore throat.

Investigations: abnormal liver function test values, elevated serum creatinine, hyperkalaemia.

The medicines like naproxen sodium may rarely (may affect up to 1 in 1000 people) be associated with liver injury.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet.

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
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 Naproxen sodium 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.

Keep the blister in the outer carton in order to protect from light.
This medicine does not require any special temperature 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 to protect the environment.

6. Contents of the pack and other information

What Naproxen sodium Krka contains
- The active substance is naproxen sodium. Each film-coated tablet contains 550 mg naproxen sodium, which is equivalent to 500 mg naproxen.
- The other ingredients are povidone K30, microcrystalline cellulose, talc and magnesium stearate in the tablet core and hypromellose, titanium dioxide (E171), macrogol 8000 and indigo carmine (E132) in the film-coating. See section 2 " Naproxen sodium Krka contains sodium".

What Naproxen sodium Krka looks like and contents of the pack
The tablets are oval, slightly biconvex, one-side scored blue film-coated tablets. Dimension: 18 x 8 mm
The tablet can be divided into equal doses.

The film-coated tablets are available in boxes of 10 x 1, 16 x 1, 30 x 1, 40 x 1 and 60 x 1 tablets in blisters.

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

Name of the Member State	Name of the medicinal product
Austria	Naproxen HCS
Belgium	Naproxen Krka
Italy	Naprossene sodico HCS
Ireland	Naproxen sodium Krka
Spain	Naproxeno sódico TAD

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