Package leaflet: Information for the patient

Paracetamol Krka 500 mg tablets
paracetamol

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 Paracetamol Krka is and what it is used for

Paracetamol Krka relieves mild to moderate pain and reduces fever.

You can use Paracetamol Krka for aches and pains of various kinds, such as headache, menstrual pains, toothache, muscle and joint pain and during fever, for example in cold.

2. What you need to know before you take Paracetamol Krka

Do not take Paracetamol Krka
- if you are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Paracetamol Krka.
If the recommended dose is exceeded, life-threatening poisoning may occur. If there is suspicion of overdose, you should contact your doctor immediately. If you take other medicines that also contain paracetamol, there is a risk of overdose.
Caution is required in weakened and exhausted patients and alcoholics.

Talk to your doctor before taking Paracetamol Krka if:
- you have impaired liver function.
- you have impaired kidney function.
- you have a poor nutritional status, eg. due to alcohol abuse, loss of appetite (anorexia) or malnutrition.
- you may need to take a smaller dose as your liver may otherwise be damaged.
- you have high fever, signs of infection (eg, sore throat) or if the pain lasts longer than 3 days.

If you take several different types of pain medication for a longer period of time, you may experience kidney damage with the risk of kidney failure. If you take Paracetamol Krka for headaches for a longer period, your headache may get worse and more frequent. Contact your doctor if you experience frequent or daily headaches. During blood and urine sample control, always mention that you take

Paracetamol Krka. This can affect the results.

Children and adolescents
Paracetamol Krka is not recommended for children under 9 years.

Other medicines and Paracetamol Krka
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes any medicines obtained without a prescription, medicines purchased abroad, herbal remedies as well as strong vitamins and minerals.

Talk to your doctor if you take:
- Medicine to treat epilepsy (e.g. phenytoin, carbamazepine and phenobarbital).
- Medicine included in some traditional herbal medicines (St John's wort (*Hypericum perforatum*)).
- Medicine to treat gout (probenecid). It may be necessary to change the dose.
- Blood-thinning medicine (eg warfarin). You may have bleeding if you take Paracetamol Krka regularly and for a long time.
- Medicine to regulate intestinal motility (metoclopramide).
- Medicine for preventing nausea and vomiting (domperidone).
- Medicine to treat tuberculosis (rifampicin).
- Medicine to treat bacterial infections (chloramphenicol).
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

If you are taking medicines for high cholesterol (cholestyramine), you should take Paracetamol Krka at least 1 hour before or 4-6 hours after this medication.

Paracetamol Krka with food and drink
If you are taking Paracetamol Krka, you should not drink alcohol.
You can take Paracetamol Krka with a meal, but it is not necessary.
You should take Paracetamol Krka tablets with a glass of water.

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
If necessary, you can take Paracetamol Krka during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced or if you need to take the medicine more often.

Breast-feeding
You can breast-feed even if you are taking Paracetamol Krka.

Driving and using machines
Paracetamol Krka has no influence on the ability to drive and use machines.

Paracetamol Krka contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium-free".

3. How to take Paracetamol 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. Paracetamol Krka contains paracetamol. Do not take with any other paracetamol-containing products. You should not exceed the recommended doses. Immediate medical advice should be sought in the event of overdosage, because of the risk of irreversible liver damage.

Adults and adolescents aged 16 years and older (≥ 55 kg of body weight)
The usual dose for adults and adolescents aged 16 years and older is 1-2 tablets (500 mg-1000 mg) 3-4 times daily, but not more than 8 tablets (4000 mg) daily. In some cases, 1 tablet of 500 mg 3-4 times daily may be sufficient. Between two intakes should be at least 4 hours.

Children from 9 to 15 years of age (30-55 kg of body weight)

Age/Body weight	**Dose (Paracetamol Krka 500 mg)**	**Maximal daily dose**
9 to 12 years of age (30-40 kg)	1 tablet (500 mg) up to 3 times daily	3 tablets (1500 mg)
12 to 15 years of age (40-55 kg)	1 tablet (500 mg) up to 4 times daily	4 tablets (2000 mg)

Between two intakes should be at least 4 hours.

Method of administration
Swallow the tablet with liquid.

Children under 9 years of age (< 30 kg of body weight)
The medicine should not be given to children under 9 years of age.

Patients with kidney insufficiency
Talk to your doctor if you have kidney problems. The dose may need to be adjusted.

Patients with liver impairment
- Talk to your doctor if you have liver problems such as liver insufficiency, Gilbert's syndrome (familial non-hemolytic jaundice) or chronic alcohol consumption. The dose may need to be adjusted and the daily dose should not exceed 2 g in these situations.

Elderly
No dosage adjustment is required in the elderly.

If you take more Paracetamol Krka than you should
Talk to your doctor or pharmacist immediately.

A larger dose of paracetamol than the recommended one is dangerous and may cause long-term damage. It can destroy the liver and in some cases also the kidneys, pancreas and bone marrow. You do not immediately get any symptoms (they usually come only after a few days). Even if you do not feel any symptoms, there may be a risk of serious liver damage. It is important that you seek medical advice as soon as possible in case of suspected overdose, even if you feel well.

If you forget to take Paracetamol Krka
Do not take a double dose to make up for a forgotten tablet.

If you stop taking Paracetamol Krka
You may safely stop taking the medicine once you no longer need it.

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.

Stop taking the medicine and contact your doctor or hospital immediately if you experience:
Very rarely (may affect up to 1 in 10 000 people):
- sudden skin rash, breathing problems and fainting (within minutes to hours) due to hypersensitivity reactions (anaphylactic reaction, allergic dermatitis);
- angioedema with symptoms like swollen face, lips, throat or tongue;
- severe peeling and rejection of the skin (toxic epidermal necrolysis);
- breathing problems (bronchospasm). These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin;
- bleeding from skin and mucosa and bruising due to changes in the blood (too few blood platelets (thrombocytopenia));
- general malaise, tendency to infections, especially throat infections, and fever, due to changes in the blood (too few white blood cells);
- anemia with jaundice due to breakdown of red blood cells (hemolytic anemia);
- serious skin rash, fever and inflammation of the skin, especially on the hands and feet, in and around the mouth (Stevens-Johnson syndrome).

Other side effects

Rarely (may affect up to 1 in 1 000 people):
- increased serum creatinine,
- urticaria,
- increased liver enzymes.

Very rarely (may affect up to 1 in 10 000 people):
- Reduced liver function. Can be serious. If you experience yellowing of the eyes (jaundice), contact your doctor.
- In long term treatment the risk of kidney damage cannot be excluded.

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 Paracetamol 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 carton, blister or bottle label after EXP. The expiry date refers to the last day of that month.

This medicine 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 Paracetamol Krka contains
- The active substance is paracetamol. Each tablet contains 500 mg paracetamol.
- The other ingredients (excipients) are sodium starch glycolate (type A), povidone, partially pregelatinised maize starch and stearic acid. See section 2 "Paracetamol Krka contains sodium".

What Paracetamol Krka looks like and contents of the pack

The tablets are white, caplet-shaped, debossed with "500" on one side and plain on other side (17.5 mm long x 7.3 mm x 5.7 mm thick).

Paracetamol Krka is available in packs containing 10, 12, 20, 30, 50, 60, 100, 105 and 120 tablets in blisters and 100 and 105 tablets in HDPE bottles.

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
Denmark, Belgium, Portugal, Spain, Sweden, Ireland,	Paracetamol Krka

This leaflet was last revised in