Package leaflet: Information for the user

Kruidvat Paracetamol 500 mg tablet, tabletten

Read all of this leaflet carefully before you start using 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.
- 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.
- Are your symptoms of pain not less after 5 days or are your symptoms of fever not less after 3 days or are they worse? Contact your doctor.

What is in this leaflet

1. What Paracetamol 500 mg tablets is and what it is used for

Paracetamol 500 mg tablet belongs to the group of pain relieving and fever lowering medicines.
Paracetamol 500 mg tablet is used for symptomatic treatment of mild to moderate pain and/or fever.
Paracetamol 500 mg tablet may be used in adults, adolescents and children but is not suitable for use in children below
8 years.

Are your symptoms of pain not less after 5 days or are your symptoms of fever not less after 3 days or are they worse? Contact your doctor.

2. What you need to know before you use Paracetamol 500 mg tablet

Do not use Paracetamol 500 mg tablet:
- if you are allergic to any of the ingredients of this medicine listed in section 6.

Warnings and precautions
Talk to your doctor or pharmacist before using Paracetamol 500 mg tablet if you suffer from:
- Hepatic or renal impairment;
- Moderate to severe renal insufficiency (inadequate activity of the kidneys)
- Mild to severe hepatic insufficiency (inadequate activity of the liver)
- Gilbert syndrome (hereditary non-haemolytic jaundice)
- Acute hepatitis
- Glucose-6-phosphate dehydrogenase deficiency (hereditary condition that is caused by a gene defect)

- Haemolytic anaemia (anaemia caused by excessive breakdown of blood)
- Dehydration
- Chronic malnourishment
- Asthma and are sensitive to aspirin (= acetylsalicylic acid)
- Alcoholism; if you consume large quantities of alcohol every day, there is a greater risk of the occurrence of harmful effects on the liver.
- Headache and you have been using analgesics for over 3 months, at least every other day

During treatment with Kruidvat Paracetamol, tell your doctor straight away if:
If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when

- paracetamol is used at regular doses for a prolonged period
- paracetamol is taken together with flucloxacillin.

Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

If your symptoms last longer than 5 days for pain or 3 days for fever, or if they return or become worse, contact your doctor.

Long-term or frequent use of paracetamol is advised against.

Consult your doctor if one of the above warnings applies to you or has done so in the past.

Other medicines and Paracetamol 500 mg tablet
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.This also applies to medicine which you can obtain without a prescription.
Different medicines can affect each other.

Contact your doctor or pharmacist before you use paracetamol if you use one of the following medicines:

- Barbiturates (group of hypnotics or anaesthetics)
- Certain antidepressants (tricyclic antidepressants)
- Probenecid (medicine for gout)
- Chloramphenicol (an antibiotic)
- Metoclopramide or domperidone (medicines for nausea and vomiting)
- Colestyramine (cholesterol lowering agent)
- Warfarin and other coumarins (blood thinners)
- Zidovudine (medicine used for the treatment of AIDS)
- Salicylamide (a painkiller)
- Isoniazid (medicine for tuberculosis)
- Lamotrigine (medicine for epilepsy)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Paracetamol can affect the test results of different laboratory tests; the uric acid test that uses tungsten phosphoric acid and the blood glucose test using glucose oxidase peroxidase.

Paracetamol 500 mg tablet with food, drink and alcohol
During treatment with paracetamol, no alcohol may be used. In case of (previous) chronic alcohol consumption, the dose of paracetamol a day may not exceed 2 grams (4 tablets). The risk of an overdose is higher in case of (previous) chronic alcohol consumption and an overdose can have a more serious course in this case. The taking of paracetamol with food and drink does not affect the efficacy of the medicine.

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.

Pregnancy:
If necessary, Paracetamol 500 mg tablet can be used 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 or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often.

Breast-feeding:
Although paracetamol is excreted in the maternal milk in small quantities, it does not have an adverse effect on children who are breastfed. In the recommended dose, paracetamol can be used in women who are breastfeeding.

Driving and using machines
As far as is known, paracetamol does not have any effect on the ability to drive or use machines.

3. How to use Paracetamol 500 mg tablet

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

Method of intake
The tablets can best be taken with plenty of water (half a glass). You can also let the tablets dissolve in water; stir the drink well and drink it all.

The usual dose is:
Adults and adolescents older than 15 years (> 50 kg body weight):
1 or 2 tablets (500-1000 mg) at a time, maximum 6 tablets (3000 mg) every 24 hours.

Children from 12 to 15 years (43-50 kg):
1 tablet (500 mg) at a time, every 4 hours, if needed, with a maximum of 4 tablets per day.

Children from 11 to 12 years (34-43 kg):
1 tablet (500 mg) at a time, every 6 hours, if needed, with a maximum of 4 tablets per day.

Children from 8 to 11 years (26-34 kg):

½ tablet (250 mg) at a time every 4 hours, or 1 tablet (500 mg) every 6 hours, if needed, with a maximum of 3 tablets per day. Other pharmaceutical forms containing paracetamol (i.e. solutions) exist as an alternative for children below 9 who might have difficulties to swallow a tablet.

- This medicine is not suitable for children below the age of 8.
- There must be an interval of at least 4 hours between two doses.
- Do not use in combination with other paracetamol-containing products.
- Do not exceed the stated dose.
- If the symptoms of pain and/or fever recur, administration can be repeated in accordance with the stated dosage regimen.
- If the pain lasts longer than 5 days or if the fever lasts longer than 3 days or becomes worse or if other symptoms occur, the treatment should be stopped and a doctor should be consulted.

The total daily dose may not be higher than 2 g/day in the following situations:
- adults who weigh less than 50 kg
- mild to moderate hepatic insufficiency, Gilbert syndrome (familial non-haemolytic jaundice)
- dehydration
- chronic malnourishment
- chronic alcoholism

Follow these instructions unless your doctor has given you different advice.
If you notice that this agent has too strong an effect or just too little effect, consult your doctor or pharmacist.

If you use more Paracetamol 500 mg tablet than you should
If you take too much of this agent, immediately contact your doctor or pharmacist. When taking a higher dose than recommended, the following symptoms can occur:
- nausea
- vomiting
- lack of appetite
- pallor
- abdominal pain

Taking several times the maximum daily dose in one go can cause very severe damage to the liver, which can result in coma and death. Symptoms of liver damage usually are not visible until two days after the overdose. However, you should immediately call for medical help after taking too much paracetamol. It may be helpful to take activated charcoal (Norit) – after consulting with a physician - lo limit the absorption of the too large quantity of paracetamol. If action is taken too late, the damage to the liver can be irreversible.

If you forget to use Paracetamol 500 mg tablet
Do not take a double dose to make up for a forgotten dose.

If you stop using Paracetamol 500 mg tablet
If you stop using the medicine, nothing in particular will happen.

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.

The following side effects can occur:

Rare (1 in 10,000 to 1 in 1,000 users)
- Different blood abnormalities, including agranulocytosis (serious blood disorder with severely decreased number of white blood cells which can result in high fever, intense throat ache and mouth ulcers), thrombocytopenia (lack of platelets with bruises and increased chance of bleeding as symptoms), thrombocytopenic purpura (red or purple discolored spots on the skin that do not blanch on applying pressure, as a result of lack of platelets), leukopenia (shortage of white blood cells with resulting sensitivity to infections) and haemolytic anaemia
- Allergies (excluding angioedema)
- Depression, confusion and hallicunations
- Tremor and headache
- Visual abnormalities
- Fluid retention (Oedema)
- Bleeding, abdominal pain, diarrhoea, nausea, vomiting
- Abnormal hepatic function, hepatic failure, hepatic necrosis and jaundice
- Itching (pruritus), rash, sweating, purpura and nettle rash/hives (urticaria)
- Dizziness, feeling unwell (malaise), fever and somnolence
- Overdose and poisoning

Very rare (less than 1 in 10,000 users)
- Pancytopenia (reduction in the number of blood cells)
- Hypersensitivity reaction as a result of which the treatment must be stopped, including angioedema, breathing difficulties, sweating, nausea, hypotension (decreased blood pressure), shock and anaphylaxis (life-threatening allergic reaction).
- Hypoglycaemia (too low blood glucose level with hunger, sweating, dizziness, palpitations and in serious cases unconsciousness as symptoms)
- Tightness of chest as a result of cramp in the muscles of the airways (bronchospasm) in people who are sensitivite to aspirin and other NSAIDs (group of painkillers with anti-inflammatory and fever lowering activity).
- Hepatic intoxication
- Skin rash (exanthema), severe skin reactions
- Cloudy urine (sterile pyuria) and renal reactions (severe renal impairment, interstitial nephritis, haematuria, anuresis)
- Severe skin reactions

Not known (cannot be estimated from the available data):
- Anemia
- Hepatitis

- Acute generalised exanthematous pustulosis, toxic necrolysis, drug-induced dermatosis (skin disorder), Stevens-Johnson syndrome (severe skin reaction with high fever, blisters on the skin, arthralgia and/or eye inflammation) and angio-oedema
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

After the long-term use of 3 to 4 grams of paracetamol a day, damage to the liver is possible. Liver damage is also possible after the use of 6 grams of paracetamol in one go (in children above 140 mg/kg).

If you experience a side effect which is not mentioned in this package insert or which you feel is serious, inform your doctor or pharmacist.

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Paracetamol 500 mg tablet

Keep this medicine out of the sight and reach of children.
This medicine does not require any special storage conditions
Do not use this medicine after the expiry date which is stated on the carton after Exp.The expiry date refers to the last day of that month.

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 500 mg tablet contains
- The active substance is paracetamol. One tablet contains 500 mg of paracetamol.
- The other substances in this medicine are maize starch, gelatin, croscarmellose sodium and magnesium stearate.

What Paracetamol 500 mg tablet looks like and contents of the pack
The tablets are (almost) white, round, flat and have a score line on one side and the inscription "Paracetamol" on the other. The tablets can be divided in equal doses.

The tablets are available in blister packs of 4, 6, 10, 20, 30, 50, 90, 100, 250 or 500 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Aurobindo Pharma B.V.
Baarnsche Dijk 1

3741 LN Baarn
Nederland

Manufacturer:
APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate
Birzebbugia, BBG 3000
Malta.

Aurex B.V.
Baarnsche Dijk 1
3741 LN Baarn
Nederland

Aurobindo Pharma B.V.
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Dit geneesmiddel is ingeschreven in het register onder:
Kruidvat Paracetamol 500 mg tablet, tabletten RVG 114335

This medicinal product is authorised in the Member States of the EEA under the following names:
België: Paracetamol Kruidvat Health 500 mg tabletten
Nederland: Kruidvat Paracetamol 500 mg tablet, tabletten

Deze bijsluiter is voor het laatst goedgekeurd in maart 2025