Package leaflet: Information for the user

Paracetamol Kappler 500 mg, tabletten
paracetamol

[For medicines available only on prescription – to be deleted if not applicable]
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.

[For medicines available without a prescription – to be deleted if not applicable]
Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet
1. What <Product name> is and what it is used for
2. What you need to know before you take <Product name>
3. How to take <Product name>
4. Possible side effects
5. How to store <Product name>
6. Contents of the pack and other information

1. What <Product name> is and what it is used for

<Product name> belongs to the group of medicines, which have an analgesic and fever-reducing effect.

You can take <Product name> for the symptomatic treatment of mild to moderate pain such as headache, menstrual pain, toothache, and to reduce fever.

<Product name> 500 mg tablets are indicated in adults, adolescents and children 6 years and older, weighing at least 22 kg.

Contact your doctor if you feel worse or if you do not feel better within 3 days.

2. What you need to know before you take <Product name>

DO NOT take <Product name> 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 <Product name> if you:
- if you are a chronic alcoholic
- if you suffer from impaired liver function (hepatitis, Gilbert's syndrome)
- if you have pre-existing kidney damage
- if you are taking other medicines that impair liver function
- if you have a hereditary deficiency of the enzyme glucose-6-phosphate dehydrogenase, which can lead to severe anaemia, also known as favism
- if you have haemolytic anaemia (anaemia due to the breakdown of red blood cells)
- in cases of a deficiency of the protein glutathione, which is involved in liver metabolism (e.g. in cases of malnutrition or alcohol abuse)
- in cases of fluid deficiency in the body (dehydration), e.g. due to low fluid intake, diarrhoea or vomiting
- in chronic malnutrition
- for a body weight below 50 kg
- in older patients
- are an asthmatic patient who is sensitive to acetylsalicylic acid

During treatment with <Product name>, tell your doctor straight away 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 or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, loss of appetite, feeling sick (nausea) and being sick (vomiting).

Do not take more of this medicine than recommended as it can cause severe liver damage.

Exceeding the recommended dose can lead to life-threatening poisoning. If an overdose is suspected, seek medical advice immediately.

If you are taking other medicines that also contain paracetamol, there is a risk of overdose.

If you take several different types of painkillers at the same time for a long period of time, you may suffer kidney damage with a risk of kidney failure.

If you have a high fever, signs of another infection or if the symptoms last longer than 3 days, contact your doctor.

If you take this medicine for headaches for a longer period of time, your headaches may get worse and more frequent. Contact your doctor if you experience frequent or daily headaches.

Effects on laboratory results
Uric acid and blood sugar levels may be affected.

Children
Do not use this medicine in children under 6 years of age. Other pharmaceutical forms are available for this patient group.

Other medicines and <Product name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Contact your doctor or pharmacist before taking paracetamol if you are taking any of the following medicines:

- barbiturates (a group of sleeping pills and anaesthetics)
- certain antidepressants (including tricyclic antidepressants and St John's wort)
- certain anti-epileptic medicines (lamotrigine, phenytoin, phenobarbital, carbamazepine, primidone)
- probenecid (a medicine for gout)
- rifampicin (an antibiotic)
- metoclopramide or domperidone (medicines for nausea and vomiting)
- warfarin and other coumarins (blood thinners)
- zidovudine (a medicine used to treat AIDS)
- salicylamide (a painkiller)
- isoniazid (a medicine for tuberculosis)
- medicines that slow down the emptying of the stomach
- other medicines that affect liver function
- flucloxacillin (an antibiotic: a medicine that kills bacteria). This may pose a serious risk of blood and fluid imbalances (known as metabolic acidosis, which causes your blood to become acidic) that require urgent treatment (see section 2)
- medicines to lower high blood lipid levels (cholestyramine)

<Product name> with alcohol
Do not drink alcohol whilst taking this 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, <Product name> 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.

You should not take this medicine during pregnancy for long periods of time, in high doses or in combination with other medicines, as its safety in these cases has not been established.

Breast-feeding
Although paracetamol is excreted in small quantities in breast milk, it does not have any adverse effect on children who are breast-fed. Paracetamol can be used at the recommended dose for a short time while breast-feeding.

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 take <Product name>

[For medicines available only on prescription – to be deleted if not applicable]
Always take this medicine exactly as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

[For medicines available without a prescription – to be deleted if not applicable]
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Never take more <Product name> than described in the dosing instructions. You should take the lowest possible dose needed for the shortest possible time. Do not exceed the maximum daily dose.

Dose

Adults and adolescents from 15 years of age (≥ 55 kg)
500 mg to 1 000 mg at a time, 3-4 times a day. However, not more than 3 000 mg per day.

Dosing interval: There should be a minimum of 4 hours between each dose.

Paediatric population
The dosage is based on the information in the table below. Paracetamol is dosed according to body weight and age, usually at 10 to 15 mg/kg body weight as a single dose, up to a maximum of 60 mg/kg body weight as a total daily dose.

Children from 6-15 years of age
The dose depends on the child's weight.
Children may receive 50 mg/kg/day divided into 3-4 doses (see “Dosage table children from 6-15 years of age”).

Dosage table children from 6-15 years of age:

Body weight	**Age**	**Dose**	**Max. daily dose**
22-30 kg	6-9 years	250 mg (1/2 tablet) max. 4-6 times within a 24-hour period	1 000-1 500 mg
30-40 kg	9-12 years	500 mg (1 tablet) max. 3-4 times within a 24-hour period	1 500-2 000 mg
40-55 kg	12-15 years	500 mg (1 tablet) max. 4-6 times within a 24-hour period	2 000-3 000 mg

Dosing interval: a minimum of 6 hours should pass between each dose. Maximum treatment time without doctor's instructions is 3 days.

Children < 6 years of age
Do not use <Product name> 500 mg tablets. This medicine is not appropriate for dosing in children younger than 6 years. More suitable formulations are available for these children.

Special patient groups

Patients with kidney problems
In patients with kidney dysfunction, the dose must be reduced or the interval between doses extended.
A total daily dose of 2 g must not be exceeded without medical advice.

Severe kidney problems
In patients with severe kidney problems (creatinine clearance lower than 10 ml/min), the interval between doses must be at least 8 hours.

Adults:

Glomerular filtration rate	**Paracetamol dose**

10-50 ml/min	500 mg every 6 hours
< 10 ml/min	500 mg every 8 hours

Patients with liver problems
In patients with liver problems or Gilbert's syndrome (familial non-haemolytic jaundice), the dose must be reduced or the interval between doses extended.
A total daily dose of 2 g must not be exceeded without medical advice.

Elderly patients
Experience has shown that no special dose adjustment is necessary.
However, a dose reduction or prolongation of the dosing interval may be necessary in debilitated, immobilised elderly patients with liver or kidney problems.
Without medical advice, the maximum daily dose of 60 mg/kg body weight (up to a maximum of 2 g/day) should not be exceeded in the following cases:
- a body weight below 50 kg
- chronic alcoholism

Method of administration
For oral use.
You should take the tablets with a glass of water.
You can take <Product name> with a meal, but this is not necessary. If you take the tablet with food, the onset of the effect is delayed. For faster pain relief, take the tablets on an empty stomach, especially if your meal is high in carbohydrates.

Tablets have a break-line, allowing them to be divided in equal doses and to be taken as half or a whole (see section dosage table above).

If you take more <Product name> than you should
The total dose of paracetamol must not exceed 3 000 mg paracetamol per day for adults and adolescents aged 15 years and older or weighing 55 kg or more, and 60 mg/kg/day for children.
In case of overdose, symptoms generally appear within 24 hours and include nausea, vomiting, loss of appetite, paleness and abdominal pain.

If a larger amount than recommended has been taken/used, seek medical assistance immediately!

If you forget to take <Product name>
Do not take a double dose to make up for a forgotten dose. Just continue with the recommended dosage schedule.

If you stop taking <Product name>
The use of <Product name> can be stopped suddenly without any consequences.
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.

Serious side effects
If you are affected by any of the following side effects **contact a doctor or emergency room immediately**:

Very rare (may affect up to 1 in 10 000 people):

- bleeding from skin and mucous membranes and bruising due to changes in the blood (too few platelets)
- general lethargy, tendency to inflammation (infections) especially sore throat and fever due to changes in the blood (too few white blood cells). Can become serious
- severe anaemia with jaundice
- sudden skin rash, difficulty breathing and fainting (within minutes to hours), allergic eczema (including rash (hives) and swelling) due to hypersensitivity (anaphylactic reaction). Please call 112, especially if there is swelling of the face, lips and tongue as this can be life-threatening
- blistering rash and inflammation of the skin, especially on the hands and feet and in and around the mouth, accompanied by fever (Stevens-Johnson syndrome, toxic epidermal necrolysis)
- severe peeling and rejection of skin
- difficulty breathing in people with a predisposition. Call 112 if necessary
- in long-term treatment, the possibility of kidney damage cannot be ruled out

Not known (frequency cannot be estimated from the available data):
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

Other side effects that may occur:

Rare (may affect up to 1 in 1 000 people):
- hives
- elevated liver enzymes
- elevated serum creatinine (measure of kidney function)

Very rare (may affect up to 1 in 10 000 people):
- effects on liver function, possibly with jaundice. Can be serious. If you develop jaundice, contact your doctor
- severe skin reactions

If you experience a side effect which is not mentioned in this leaflet or which you consider to be 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 <Product name>

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, bottle and blister 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 <Product name> contains

The **active** substance is paracetamol.

Each tablet contains 500 mg paracetamol.

The **other** ingredients are: pregelatinised starch (Starch 1500), maize starch, povidone K30, talc (E553b) and stearic acid.

What <Product name> looks like and contents of the pack

White to off-white, caplet-shaped tablets having a break-line on one side and plain on the other side, with a length of approximately 17 mm and a width of approximately 7 mm.
The tablet can be divided into equal doses.

The tablets are packed in blisters or unit-dose blisters manufactured of opaque PVC foil sealed with an aluminium foil or packed in HDPE bottles sealed with a liner and closed with a cap.

Pack sizes:
<Product name> 500 mg tablets is available in packs containing 10, 10x1, 12, 12x1, 16, 16x1, 20, 20x1, 24, 24x1, 30, 30x1, 40, 40x1, 50, 50x1 and 100 tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikanten
Vergunninghouder:
Kappler Pharma Consult GmbH
Fonyoder Str. 18
89340 Leipheim
Duitsland

Fabrikanten:
STADA Arzneimittel AG
Stadastraße 2 -18
61118 Bad Vilbel
Duitsland

Stada M&D S.R.L.
Strada Trascaului Nr 10
401135 Turda
Roemenië

Centrafarm Services B.V.
Van de Reijtstraat 31 E
4814NE Breda
Nederland

Fundacio Privada Dau
Carrer Lletra C De La Zona Franca 12-14
08040 Barcelona
Spanje

In het register ingeschreven onder
RVG 135241

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Duitsland	Paracetamol STADA
Frankrijk	PARACETAMOL STADA
Italië	Paracetamolo EG STADA
Nederland	Paracetamol Kappler
Spanje	Paracetamol STADAMED

Deze bijsluiter is voor het laatst goedgekeurd in oktober 2026.