Package leaflet: Information for the patient

Paracetamol 500 mg tablets

paracetamol

Rx

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 have told 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.

OTC

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 have 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 Paracetamol 500 mg tablets are and what they are used for
2. What you need to know before you take Paracetamol 500 mg tablets
3. How to take Paracetamol 500 mg tablets
4. Possible side effects
5. How to store Paracetamol 500 mg tablets
6. Contents of the pack and other information

1. What Paracetamol 500 mg tablets are and what they are used for

Paracetamol 500 mg tablets contains the active substance paracetamol which have an analgesic and fever reducing effect.
Paracetamol is used for symptomatic treatment of mild to moderate pain and/or fever.
This medicine is indicated in adults, adolescents and children from 22 kg (aged 6 years and older).
You must talk to a doctor if the pain persists beyond 5 days, the fever persist beyond 3 days or get worse, or other symptoms appear.

2. What you need to know before you take Paracetamol 500 mg tablets

Do not take Paracetamol 500 mg tablets
- if you are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
If you use other analgesics containing paracetamol you must not use paracetamol without first consulting a doctor or pharmacist. Your doctor or pharmacist will adjust the dosage, to avoid the risk of overdose.

Never take more paracetamol than what is stated in the dosing instructions. Higher doses than recommended will not lead to better pain relief, instead it increases the risk of very severe liver damage. The symptoms of liver damage usually appear after a few days. It is therefore important that you contact a doctor immediately if you have taken too high a dose, even if you are feeling fine.

Talk to your doctor or pharmacist before using Paracetamol 500 mg tablets if you:
- have liver or kidney problems or suffering from impaired liver function (liver inflammation, Gilbert's syndrome (Meulengracht's disease) or have an acute hepatitis
- have Hepatocellular insufficiency (Child-Pugh < 9)
- are underweight or malnourished
- regularly drink alcohol
- have an enzyme deficiency (glucose-6-phosphate dehydrogenase deficiency)
- are undergoing treatment with medicinal products affecting hepatic functions
- have a glutathione (antioxidant) deficiency
- have abnormal breakdown of red blood cells (haemolytic anaemia)
- are suffering from dehydration
- are an asthmatic patient who is sensitive to aspirin (acetylsalicylic acid)
- have a severe infection as this may increase the risk of metabolic acidosis. Signs of metabolic acidosis include:
    - deep, rapid, difficult breathing
    - feeling sick (nausea), being sick (vomiting)
    - loss of appetite
- are elderly

Contact a doctor immediately if you get a combination of these symptoms.
You may need to avoid using this product altogether or limit the amount of paracetamol that you take.

During treatment with paracetamol, tell your doctor straight away:
if you suffer from severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood and cause organ damage), or if you suffer from malnutrition or chronic alcohol illness, or if you additionally take flucloxacillin (an antibiotic).

In patients in these situations, a severe illness has been reported which is called metabolic acidosis (a disturbance of the blood and fluid balance). It occurred when paracetamol was used in normal quantities over a prolonged period or when paracetamol was used together with flucloxacillin.

Signs of metabolic acidosis may include severe breathing difficulties with deep, rapid breathing, drowsiness, nausea and vomiting

In general, habitual use of painkillers, particularly when combining several pain-relieving active substances, may lead to permanent kidney damage with the risk of kidney failure (analgesic nephropathy).

Headaches, as well as fatigue, dizziness, muscle pain, nervousness may occur after sudden discontinuation of prolonged use of high-dose painkillers such as paracetamol. In that event, ask your doctor or pharmacist for advice.

Children and adolescents
Do not give Paracetamol 500 mg tablets 500 mg tablet to children under the age of 6 years or under 22 kg body weight.

Other medicines and Paracetamol 500 mg tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines; particularly colestyramine (to lower blood cholesterol).
Paracetamol may increase the effect of blood thinning medicines (anticoagulants e.g. warfarin). If

you take blood thinning medicines and you need to take a pain reliever daily, then talk to your doctor because of the risk of bleeding. However, you can still take occasional doses of Paracetamol 500 mg tablets at the same time as anticoagulants.

Paracetamol dose should be reduced with concomitant intake of probenecid as this inhibits the binding of paracetamol to glucuronic acid, leading to a reduction in paracetamol clearance.

Paracetamol should be administered with zidovudine (AZT) only on medical advice due to the susceptibility of neutropenia development increasing.

Please inform your doctor or pharmacist if you are taking:
Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Particular caution should be exercised with concomitant intake of paracetamol with medicines that lead to enzyme induction, as well as with potentially hepatotoxic substances, e.g. phenytoin, carbamazepine, phenobarbital and rifampicin.

Concomitant intake of agents which slow gastric emptying as the absorption and onset of action of paracetamol may be delayed and agents which accelerate gastric emptying, e.g. metoclopramide, as it speeds up onset of action and absorption. Your doctor or pharmacist should also be advised if domperidone (for nausea [feeling sick] or vomiting [being sick]) has been taken.

Paracetamol may increase the effect of vitamin K antagonists, effect of **warfarin and other coumarins** especially with regular intake of high paracetamol doses, may be occasional doses have no significant effect. Paracetamol may also reduce the effects of lamotrigine, a drug used to treat epilepsy.

Effects on laboratory results
Intake of paracetamol can affect uric acid tests using phosphotungstic acid and blood sugar tests using glucose oxidase-peroxidase.

Paracetamol 500 mg tablets with alcohol
Alcohol should not be used during the treatment with paracetamol.

Pregnancy, breast-feeding and fertility
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If necessary, paracetamol 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 pharmacist if the pain and/or fever are not reduced or if you need to take the medicine more often.

Paracetamol 500 mg tablets in recommended doses may be used during breast-feeding.

There are no adequate clinical data available on male or female fertility.

Driving and using machines
Paracetamol 500 mg tablets has no or negligible influence on the ability to drive and use machines.

3. How to take Paracetamol 500 mg tablets

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

OTC

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The analgesic and antipyretic efficacy of paracetamol in humans is related to the dose administered. The oral dose is based upon age and body weight (BW); the usual single dose is 10 – 15 mg/kg BW up to a maximum of 60 mg/kg (BW) as the total daily dose. In each case, the dosing interval depends on the symptoms and maximum total daily dose. It should be no less than 4-6 hours.
The lowest dose necessary to achieve efficacy should be used.

Do not exceed the stated dose.

The tablets can be divided into equal doses.

Recommended dose:

Body weight (age)	**Single dose paracetamol**	**Number of tablets at a time**	**Max. daily dose (24 h) Paracetamol**
22 kg- 30 kg (children 6 – 9 years approximately)	250 mg	1/2 of 500 mg	1,000 – 1,500 mg (Maximum 3 tablets)
31 kg - 40 kg (children 10 - 12 years approximately)	500 mg	1	1,500 - 2,000 mg ((Maximum 4 tablets)
41 kg – 55 kg (children 13 – 15 years approximately	500 mg	1-1½	2,000 - 3,000 mg (Maximum 6 tablets)
>55 kg (adults and adolescents from 15 years of age and over)	500 mg	1-2	4,000 mg (Maximum 8 tablets)

This medicinal product is not intended for use in children below 22 kg body weight (under 6 years of age) due to inadequacy of dose/unfeasibility of appropriately dosing these patients. For children under the age of 6 years, more suitable formulations are available.

If symptoms of pain persist for more than 5 days and fever persist more than 3 days or in case of signs of infection consult your doctor or pharmacist.
The patient's caregiver should be advised to contact a physician if high fever, signs of infection, or symptoms persist after more than 2 days of treatment in children under 12 years of age.

Patients/users/children between 6 and 9 years of age (between 22 and 30 kg): the maximum single dose per intake is half a tablet (250 mg paracetamol).

Elderly patients
Dose adjustment is not required in the elderly. However, it should be taken into account that renal and/or hepatic insufficiency is more common in the elderly.

Renal impairment
In case of renal impairment, patients are advised to consult a doctor or pharmacist before taking this medicine. The minimum interval between each administration and the maximum daily dose should follow the below schedule:

Creatinine clearance	**Administration interval**	**Maximum daily dose (24 h) of paracetamol** *(number of tablets)*
cl 10-50 mL/min	500 mg every 6 hours	2000 mg *(4 tablets)*
cl <10 mL/min	500 mg every 8 hours	1500 mg *(3 tablets)*

Hepatic impairment
In the presence of hepatic insufficiency or Gilbert's syndrome, patients are advised to consult a doctor or pharmacist.

Without medical advice, a maximum daily dose of 60 mg/kg body weight (till a maximum of 2,000 mg/day) should not be exceeded in the case of:
- Body weight below 50 kg
- Liver impairment
- Gilbert's syndrome (familial non-haemolytic jaundice)
- Chronic alcohol abuse
- Dehydration
- Chronic malnutrition

Chronic alcohol consumption or impaired liver function may lower the paracetamol toxicity threshold. In these patients, the dose must be reduced or the dosing interval prolonged. Ask your doctor or pharmacist for advice.

Method of administration

Oral use.

The tablet should be swallowed with a glass of water.

Treatment should be as short as possible at the lowest possible dose.
- Not suitable for children under 6 years old.
- After taking your dose of paracetamol, you should wait at least 4 hours before taking another dose, even if the symptoms return earlier.
- Do not exceed the indicated dosage per 24 hours due to the risk of serious damage to the liver.
- Do not use it in combination with other products containing paracetamol.
- When the symptoms of pain and/or fever reappear, administration can be repeated according to the indicated dosing schedule.
- If the pain persists for more than 5 days or the fever lasts more than 3 days or gets worse, then stop the treatment and contact your doctor.

If you notice that Paracetamol 500 mg tablets tablet is working too strongly or too little, consult your doctor or pharmacist.

If you take more Paracetamol 500 mg tablets than you should
If you take too much paracetamol tablet, contact your doctor or pharmacist immediately. If you take a higher dose than indicated, nausea, vomiting and a lack of appetite may occur.
Taking the maximum daily dose several times at once can cause very serious damage to the liver. Unconsciousness usually does not occur. You should seek medical attention immediately, even if you don't have any symptoms. If you act too late, the damage to the liver can be irreparable. Overdose can lead to severe liver damage, coma, and death.

If you forget to take Paracetamol 500 mg tablets
Do not take a double dose of paracetamol tablet to make up for a forgotten dose. Just continue with the indicated dosing schedule.

If you stop taking Paracetamol 500 mg tablets
The use of paracetamol tablet can be stopped suddenly without 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.

Rare (may affect up to 1 in 1,000 people)
- Elevation of liver transaminases, hepatic dysfunction, hepatic failure, hepatic necrosis, jaundice.
- Pruritus, rashes, sweating, angioedema, urticaria.
- Headache
- Abdominal pain, diarrhea, nausea, vomiting and constipation.
- Dizziness, malaise
- Overdose and intoxication

Very rare (may affect up to 1 in 10,000 people)
- Thrombocytopaenia, leukopenia, pancytopenia, neutropenia, haemolytic anaemia, agranulocytosis.
- Anaphylaxis (requiring discontinuation of treatment), cutaneous hypersensitivity reactions, including, among others, skin rashes.
- Serious skin reactions (drug-induced Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalised exanthematous pustulosis (AGEP).
- Bronchospasm in patients sensitive to aspirin and other NSAIDs.
- Hepatotoxicity
- Sterile pyuria (cloudy urine).

Frequency "Not known" (frequency cannot be estimated from the available data):
- Anaemia
- Hepatitis
- Exanthema
- Nephropathies (interstitial nephritis, tubular necrosis) following prolonged use of high doses

Frequency "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)

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 500 mg tablets

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 blister, bottles and the carton 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 500 mg tablets contains
The active substance is paracetamol. Each tablet contains 500 mg paracetamol.
The other ingredients are: Pregelatinised starch, Povidone K30, Stearic acid.

What Paracetamol 500 mg tablets look like and contents of the pack

Paracetamol 500 mg tablets are white to off-white oblong biconvex tablets, breakline with 5 on one side of the line and 00 on the other side of the line on one side of the tablet and breakline on the other side. The tablet has dimensions: approx. 7.2 mm x 16.3 mm.

Paracetamol 500 mg tablets are packed in:
PVC/aluminium non-perforated blister packs containing 10, 16, 20, 30, 50, 100 tablets.
PVC/aluminium perforated unit-dose blister packs containing 10x1, 16x1, 20x1, 30x1, 50x1, 100x1 tablets.

HDPE bottles with polypropylene child-resistant closure or continuous thread caps containing 100, 120, 300, 400, 1000 tablets per bottle.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva B.V.
Swensweg 5
2031 GA Haarlem
The Netherlands

Manufacturers
Teva Pharmaceutical Works Private Limited Company, Pallagi út 13., Debrecen, H-4042, Hungary

Merckle GmbH, Graf-Arco-Str. 3, Ulm, 89079, Germany.

Teva Czech Industries s.r.o, Ostravska 305/29 Komarov, 747 70 Opava, Czech Republic

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

Belgium	Paracetamol Generics 500 mg / 1000 mg
Bulgaria	Paracetamol 500 mg / 1000 mg
Germany	Paracetamol-ratiopharm 500 mg / 1000 mg
Denmark	Pinex
Estonia	Paracetamol

Spain	Paracetamol-ratio 1g
Croatia	Plicet Forte 1000 mg
Hungary	MEXALEN 500 mg
Ireland	Paracetamol 500 mg tablets
Iceland	Paratabs
Lithuania	Paracetamol 500 mg
Latvia	Paracetamol 500 mg
Luxembourg	Paracetamol-ratiopharm 500 mg / 1000 mg
Norway	Pinex
Portugal	Doloramol 500 mg / Paracetamol 1000 mg
Sweden	Paracetamol

This leaflet was last revised in July 2026.