

Paracetamol

500mg Tablets

Paracetamol

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What paracetamol is and what it is used for
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4. Possible side effects
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1. WHAT PARACETAMOL IS AND WHAT IT IS USED FOR

Paracetamol is a pain relieving, fever reducing medicinal product (analgesic and antipyretic). Paracetamol is used for symptomatic treatment of mild to moderate pain and/or fever.

2. BEFORE YOU TAKE PARACETAMOL

Do not take paracetamol

- if you are allergic (hypersensitive) to paracetamol or any of the other ingredients of paracetamol.

Take special care with paracetamol

- if you have kidney or liver disease;
- if you have impaired nutritional state e.g. caused by alcohol abuse.
- If you are taking any other paracetamol containing products.
- If you have severe haemolytic anaemia (abnormal breakdown of red blood cells)

You should not use paracetamol frequently for a long period of time, as prolonged use may cause liver problems. Discuss with your doctor or pharmacist if you intend taking paracetamol for a longer period of time.

In children treated with 60mg/kg daily of paracetamol, the combination with another antipyretic is not justified except in the case of ineffectiveness.

Caution is advised in the administration of paracetamol to patients with Severe renal insufficiency or mild to moderate hepatocellular insufficiency

Paracetamol should be used with caution in patients with mild to moderate hepatocellular insufficiency (included Gilbert's syndrome), severe hepatic impairment, acute hepatitis, in case of concomitant treatment with medicines that influences the hepatic function, G6PD deficiency, haemolytic anaemia.

The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Caution should be exercised in cases of chronic alcoholism. The daily dose should not exceed 2 g in such case.

Paracetamol should be used with caution in cases of dehydration and chronic malnutrition.

Do not use paracetamol unless prescribed by your doctor if you have an addiction to alcohol or liver damage and do not use paracetamol together with alcohol. Paracetamol does not potentiate the effect of alcohol.

If you are concomitantly taking other pain medication containing paracetamol do not use of paracetamol without first speaking to your doctor or a pharmacist.

Never take more of paracetamol than recommended. A higher dose does not increase pain relief; instead it can cause serious liver damage. The symptoms of liver damage occur first after a few days. It is therefore very important that you contact your doctor as soon as possible if you have taken more paracetamol than recommended in this leaflet.

In long-term, high-dose, incorrect use of painkillers, headaches may occur which may not be treated with higher doses of the medicine.

In general, habitual intake of painkillers, particularly a combination of several analgesic substances, can lead to permanent kidney damage with the risk of kidney failure (analgesic nephropathy).

Sudden stopping use of paracetamol following long term use may lead to headaches, fatigue, muscle pain, nervousness, dizziness or fainting. These symptoms resolve within a few days. Until this time, avoid further use of painkillers and do not restart them without medical advice.

You should not take paracetamol for long periods or at high doses without talking to your doctor or dentist (s. a.).

Children and adolescents:

Paracetamol is not recommended for children aged under 11 years.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is especially important in case of:

- chloramphenicol (to treat infections);
- zidovudine (to treat AIDS);
- rifampicin (to treat infections)
- cimetidine (to treat heartburn)
- metoclopramide or domperidone (to treat nausea and vomiting);
- colestyramine (to lower cholesterol);
- probenecid (to treat e.g. gout)
- anti-coagulants (drugs to thin the blood, e.g. warfarin), in case you need to take a pain relieving medicinal product on a daily basis over a long period.
- Glutetimide, fenobarbital, carbamazepine (to treat epilepsy)
- or the herbal remedy St. Johns Wort

Effect of the intake of paracetamol on laboratory tests: Tests for uric acid and blood sugar can be affected.

Using paracetamol with food and drink

Concurrent use of Paracetamol and consumption of large amount of alcohol should be avoided.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicines.

During pregnancy, paracetamol should not be taken for long periods, at high doses or in combination with other medicinal products.

Therapeutic doses of paracetamol may be used during pregnancy or breast-feeding.

Driving and using machines

Paracetamol does not influence your ability to drive or use machines.



3. HOW TO TAKE PARACETAMOL

Always take paracetamol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Do **not** exceed the stated dose.
The dose of paracetamol is based upon age and body weight; the usual dose is 10–15 mg paracetamol per kg body weight as a single dose, up to a total daily dose of 60mg/kg body weight.

Paracetamol 500mg tablets

Adults and adolescents weighing more than 65 kg
The usual dose is 500 mg to 1000 mg (1 to 2 tablets) every 4 hours as needed, to a maximum of 3000 mg (6 tablets) daily.

Adolescents weighing between 44 and 65 kg (from 12 years of age)
The usual dose is 500 mg (1 tablet) every 4 hours as needed, to a maximum of 3000 mg (6 tablets) daily.

Children weighing between 33 and 43 kg (about 11-12 years)
The usual dose is 500 mg (1 tablet) every 6 hours as needed, to a maximum of 2000 mg (4 tablets) daily.

Children under 11 years of age: not recommended.

If your symptoms worsen or do not improve after 3 days, or if you have high fever you must contact a doctor.

Special groups of patients

Elderly patients
Dose adjustment is not required in the elderly.

Impaired liver or kidney function
In patients with impaired liver or kidney function, the dose must be reduced or the dosing interval prolonged. Ask your doctor or pharmacist for advice.

Children and adolescents with small body weight.

Paracetamol 500 mg is not suitable for children under 11 years of age and under 33 kg body weight respectively, since the dose strength for this age group is not suitable. For this patient group, other formulations and dose strengths are available.

Method of administration
Tablets for Oral use.
Swallow the tablets with a glass of water

If you take more paracetamol than you should
Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

If you forget to take paracetamol
If you forget to take a dose, take it as soon as you remember, then carry on as before. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, paracetamol can cause side effects, although not everybody gets them.

Rare side effects (affect 1 to 10 users in 10,000):
Hives (urticaria); increased liver enzymes; increased creatinine in serum, itching (pruritus), sweating, small bleedings in the skin (purpura).

Blood disorders (reduction in platelets, white blood cells and neutrophils in the blood, haemolytic anaemia); narrowing of the airways in predisposed patients; allergic reactions (hypersensitivity reactions inclusive skin rash and angioedema with symptoms like swollen face, lips, throat or tongue); stomach pain, diarrhoea, nausea (feeling sick) vomiting, bleeding (haemorrhage), yellowing of the

eyes (jaundice), swelling of the ankles (oedema)
Liver, kidney, urinary problems as well as inflammation of the pancreas (pancreatitis).

In long-term treatment the possibility of kidney damage cannot be ruled out.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PARACETAMOL

Keep out of the reach and sight of children.

Do not use paracetamol after the expiry date which is stated on the blister, carton or bottle. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

This medicinal product does not require any special storage conditions.

6. FURTHER INFORMATION

What paracetamol contains
The active substance is paracetamol
Paracetamol contains 500mg of paracetamol.

The other ingredients are:
Sodium starch glycolate, Povidone (K-30),
Pre-gelatinised maize starch, Stearic acid

What paracetamol looks like and contents of the pack

Paracetamol 500 mg tablets
White, caplet-shaped tablet, debossed with "500" on one side and plain on other side.
Pack sizes:
Blister:
10 / 12 / 20 / 24 / 30 / 96 and 100 tablets

HDPE bottle
100 and 250 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Millmount Healthcare Limited
Unit 1, Donore Road Industrial Estate,
Drogheda, County Louth, Ireland.

Manufacturer
Millmount Healthcare Limited
Block 7, CityNorth Business Campus,
Stamullen, County Meath, Ireland.

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

DE	Paramill 500mg Tabletten
IT	Paracetamolo EG
IE	Paracetamol 500mg tablets

This leaflet was last approved in 05/2013.