

Package leaflet: Information for the user

Paracetamol 500 mg tablets paracetamol

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 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 of fever and 5 days of pain or if other symptoms appear.

What is in this leaflet

1. What Paracetamol is and what it is used for
2. What you need to know before you take Paracetamol
3. How to take Paracetamol
4. Possible side effects
5. How to store Paracetamol
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1. What Paracetamol is and what it is used for

Paracetamol contains the active substance paracetamol which is a painkiller and also reduces your temperature when you have a fever. It is recommended for the short-term treatment of mild to moderate pain such as headache, toothache, muscle and joint pain and menstrual pain. It also relieves fever associated with common colds and flu.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days of fever and 5 days of pain or if other symptoms appear.

Paracetamol is indicated in adults and adolescents aged 12 or older.

2. What you need to know before you take Paracetamol

Do not take Paracetamol if:

- you are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6);

Warnings and precautions

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.

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, feeling sick (nausea) and being sick (vomiting).

Talk to your doctor or pharmacist before taking Paracetamol.

- if you have kidney problems
 - if you have liver problems
 - if you have a hereditary disease called Gilbert's syndrome
 - if you are taking other medicines affecting liver function
 - if you have Glucose-6-phosphate dehydrogenase deficiency (an enzyme deficiency)
 - if you have haemolytic anaemia (abnormal breakdown of red blood cells)
 - if you have glutathione deficiency
 - if you are dehydrated or if your doctor told you that you are suffering from chronic malnutrition
 - if you weigh less than 50kg
 - if you are elderly
 - if you have alcohol problems or liver damage and also do not use Paracetamol with alcohol.
 - if you use other analgesics containing paracetamol you must not use Paracetamol
 - if you have been diagnosed with asthma and are also sensitive to acetylsalicylic acid (an anti-inflammatory medicinal product) because there is a risk of bronchospasm
- Talk to a doctor if the pain lasts more than 5 days or the temperature remains high or if these symptoms are accompanied by cough, headache, rash, nausea and vomiting.

Children and adolescents

Paracetamol is not recommended for children under 12 years of age. Other formulations containing paracetamol are available.

Other medicines and Paracetamol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:

- The concomitant use of Paracetamol might potentiate the effect of coumarin anticoagulants (blood thinning medicine).
- Cholestyramine (to lower cholesterol), reduces the absorption of Paracetamol. Metoclopramide and domperidone (for nausea and vomiting) may increase the rate of absorption of Paracetamol. However, concurrent use does not need to be avoided.
- The concomitant use of Paracetamol with phenothiazines may lead to hypothermia.
- Enzyme inducers, such as phenytoin, carbamazepine, phenobarbital, isoniazid, St Johns wort may increase the risk of hepatotoxicity.
- Probenecid (a medicine for gout).
- Oral contraceptives and Rifampicin reduce the effects of Paracetamol.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Paracetamol with food, drink and alcohol

Paracetamol must not be taken together with alcohol due to a risk of an increase in the toxic effect of paracetamol on the liver.

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 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 if the pain and/or fever are not reduced or if you need to take the medicine more often.

You can take this product whilst breastfeeding.

Driving and using machines

Paracetamol does not affect the ability to drive and use machines.

Paracetamol contains sodium and wheat starch

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

This medicine contains only very low levels of gluten (from wheat starch) and is very unlikely to cause problems if you have coeliac disease.

One tablet contains no more than 3 micrograms of gluten. If you have wheat allergy (different from coeliac disease) you should not take this medicine.

3. How to take Paracetamol

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.

Paracetamol should be used at the lowest effective dose for the shortest possible time. Dose depends on age and body weight, generally 10 to 15 mg/kg body weight as a single dose, up to a maximum of 60 mg/kg body weight as the total daily dose, not exceeding 3000 mg.

Doses recommended as per the table below:

Age	Body weight	Single dose	Maximum daily dose	Dosing interval
12 – 15 years	40 – 55 kg	500 mg (1 tablet)	2 - 3 g (maximum of 4 - 6 tablets per 24 hours)	at least 4 – 6 hours
> 15 years	40 – 55 kg	500 mg (1 tablet)	3 g (maximum of 4 - 6 tablets per 24 hours)	at least 4 – 6 hours
	> 55 kg	500 – 1,000 mg (1-2 tablets)	3 g (maximum of 6 tablets per 24 hours)	

Paracetamol is not recommended for children under 12 years of age. Other formulations containing paracetamol are available.

The length of the course of treatment without a consultation with a doctor must not exceed, for adults and children 12 years and over, 3 days for fever and 5 days for pain.

Elderly

Normal adult dosage of paracetamol is usually appropriate. However, in frail, immobile elderly subjects or in elderly patients with renal or hepatic impairment, or patients who have Gilbert's syndrome, a reduction in the amount or frequency of dosing may be appropriate.

Use in kidney or liver impairment

If you have been diagnosed with kidney or liver problems, please consult your doctor or pharmacist. You may need to take a lower dose or increase the length of time between doses.

Method of administration

Swallow the tablet with water.

If necessary, the tablet can be divided in two equal parts. Check with your doctor or pharmacist if you are not sure about anything.

If you have taken more of Paracetamol than you should

If you have used more Paracetamol than you should, immediate medical advice should be sought because there is a risk of irreversible liver damage, even if you feel well.

To prevent liver damage, it is important that your doctor can start treatment as soon as possible. The sooner you receive treatment of an overdose the better are the chances to prevent damage to the liver. These may not appear even in an overdose situation.

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.

Agranulocytosis

Stop taking Paracetamol and immediately contact a doctor if you experience one of the following symptoms (agranulocytosis): fever coupled with a severely deteriorated general state of health or a fever in combination with sore throat/mouth or difficulty urinating, which are signs of infection. As Paracetamol can in rare cases lead to a deteriorated immune system due to a lack of white blood cells, infections can become serious. For this reason, it is also important that you inform health care personnel about your medication

Stevens-Johnson syndrome / TEN/AGEP

Stop taking Paracetamol and immediately contact a doctor or go to the emergency department if you experience the following symptoms: Extremely intense and serious skin reactions, such as Stevens-Johnson syndrome, toxic epidermal necrolysis and acute generalized exanthematous pustulosis (AGEP) have been reported during use of Paracetamol.

The adverse reaction of the skin may appear as rashes with or without blisters. Skin irritation, sores or swelling in the mouth, throat, eyes, nose and around the genitals (Stevens-Johnson syndrome) and fever and flulike symptoms may occur. The skin rashes may develop into serious widespread skin damage (peeling of the epidermis and superficial mucous membranes) with life-threatening consequences.

If symptoms of AGEP appear, it usually occurs in conjunction with the start of treatment.

Angioedema

Stop using Paracetamol and immediately contact a doctor if you experience any of the following symptoms (angioedema): swelling of the face, tongue or throat; difficulty swallowing; hives and breathing difficulties.

In rare cases allergic reactions are observed – itching, rash, very rarely – changes in the blood count, e.g. thrombocytopenia (decrease of the number of blood plates).

Rare (may affect up to 1 in 1000 users):

- Angioedema, very severe allergic reaction (swelling of the face, tongue or throat, difficulty swallowing, hives and difficulty breathing)
- Allergic reactions such as skin rashes and hives. Even less severe forms of skin reactions, rashes and itching may occur.
- Liver impact. This can be very serious and can produce symptoms such as fatigue, nausea, vomiting, stomach upset and loss of appetite.

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

- Bleeding from the skin and mucous membranes and bruises, general lethargy, tendency to inflammation (infections) especially sore throat and fever due to changes in the blood (decreased number of white blood cells and platelets).
- Severe breathing difficulties with panting breathing.
- Kidney side effects.
- Paleness, fatigue and jaundice due to severe anaemia.
- Very rare cases of severe skin reactions have been reported.
- Anaphylaxis: hypersensitivity reaction with fever, skin rash, swelling, and sometimes a drop in blood pressure.

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).

In case of long-term use of high doses of Paracetamol, the functions of the liver may be impaired (the skin and the eyes become yellow, nausea, stomach pain or discomfort, easily getting tired).

If any of the side effects becomes serious or if you notice other side effects, which are not listed in this leaflet, please, talk to your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor. 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

Keep this medicine out of the sight and reach of children.

Store below 25°C.

Do not use this drug after the expiry date which is stated on the cardboard package. The expiry date refers to the last day of the month.

Do not use this drug if you notice a breach of the integrity of the blister or a change in the colour of the tablets.

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 contains

- The active substance is: paracetamol. Each table contains 500 mg paracetamol.
- The other ingredients (excipients) are: wheat starch; cellulose, microcrystalline (PH 101); sodium starch glycolate (type A); magnesium stearate (vegetable grade); talc; povidone (K25); silica, colloidal, anhydrous (aerosil 200/ hydrophilic pyrogenic silica).

What Paracetamol looks like and contents of the pack

Round, flat tablets, with a facet and a score line on one side, with a 13 mm diameter and 4 mm thickness. Colour – white to almost white.

Paracetamol 500mg tablets packs in PVC/aluminium blisters in packs of 12, 20 and 24 tablets
Not all packs sizes may be marketed.

Marketing Authorisation Holder

Bluefish Pharmaceuticals AB
P.O. Box 49013
100 28 Stockholm
Sweden

Manufacturer

Inbiotech Ltd.
5A Triaditza Str.
Sofia 1000
Bulgaria

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

Ireland	Paracetamol 500mg tablets
Portugal	Paracetamol Bluefish
Sweden	Paracetamol Bluefish

This leaflet was last revised in