



**PACKAGE LEAFLET:
INFORMATION FOR THE PATIENT**

**Paracetamol
500 mg tablets**

Paracetamol

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.

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
6. Contents of the pack and other information

1. What Paracetamol is and what it is used for

Paracetamol contains active substance Paracetamol which belongs to a group of medicines called analgesics (painkillers).

Paracetamol is used to relieve pain and help reduce fever. The tablets can treat mild to moderate pain and/or fever [e.g. headache and toothache].

Paracetamol tablets may be used in adults and adolescents but is not suitable for use in children below 10 years.

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

Talk to your doctor or pharmacist before taking Paracetamol

- if you have kidney or liver disease (including Gilbert's syndrome or acute hepatitis)
- if you have a deficiency of a certain enzyme called glucose-6-phosphatase
- if you have hemolytic anemia (abnormal breakdown of red blood cells).
- if you regularly take large amounts of alcohol. Never take more than 2000 mg a day.
- if you are asthmatic sensitive to acetylsalicylic acid.
- in case of dehydration or chronic malnutrition

When you are taking any medication to treat epilepsy you should consult your doctor before taking paracetamol, because when used at the same time, it decreases the effectiveness and potentiates the risk of liver damage by paracetamol, especially in treatments when using high acetaminophen doses.

In cases of high fever, signs of a secondary infection, or persistence of your symptoms for more than three days, consult your doctor or pharmacist.

Headaches caused by overuse of analgesics should not be handled by increasing the dose. In those cases, the use of analgesics should be taken after consulting a doctor.

“Do not take more paracetamol than recommended in section 3. How to take paracetamol. Concomitant use of this medication with other medicines containing paracetamol, such as flu and cold medicines should be avoided since high doses may lead to liver damage. Do not use more than one drug containing paracetamol without talking to your doctor”.

Other medicines and Paracetamol

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

Black

Do not use Paracetamol in combination with other paracetamol-containing medicines.

Please talk to your doctor before you take paracetamol in case you use one of the following medicines:

- metoclopramide or domperidone (medicines used to treat nausea and vomiting)
- colestyramine (used to lower your cholesterol)
- warfarin and other coumarin derivatives (medicines to thin the blood), particularly in case you need to take paracetamol on a daily basis over a long period of time
- salicylamide (a pain killer)
- probenecid (a medicine used to treat gout)
- isoniazid or rifampicin (a medicine used to treat tuberculosis)
- lamotrigine or phenytoin (a medicine used to treat epilepsy)
- barbiturates or carbamazepines (medicines that cause relaxation and sleepiness)
- St. John's wort (a medicine used to treat depression)
- chloramphenicol (an antibiotic)
- zidovudine (a medicine used to treat AIDS)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

If you are going to have any laboratory tests (such as a blood test, urine analysis, skin allergy test, etc.), you should tell your doctor that you are taking this medicine as it could affect the results of these tests.

Paracetamol with food and drink and alcohol

Alcohol should be avoided when taking Paracetamol

Pregnancy, breast-feeding and fertility

Pregnancy

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.

Breast-feeding

Paracetamol is excreted in breast milk but in insignificant amounts. Therapeutic doses of paracetamol may be used during breast-feeding.

Fertility

No detrimental effects on fertility upon normal use of paracetamol are known.

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.

Driving and using machines

Paracetamol is not expected to impair your ability to drive or to operate machinery.

Paracetamol contains sodium

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

3. How to take Paracetamol

Dosage

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

The recommended dose is:

Adults, the elderly and children 16 years and over (above 55 kg body weight):

Take one or two Paracetamol 500 mg tablets up to 4 times a day. The maximum daily dose of Paracetamol must not exceed 6 tablets (3000 mg).

Children 10 to 15 years of age (40-55 kg body weight)

Take one Paracetamol 500 mg tablet up to 4 times a day. The daily dose must not exceed 4 tablets (2000 mg). Not recommended for children under 10 years of age.

The dose should not be repeated more frequently than every 4 hours and not more than 4 doses should be taken in any 24-hour period.

The tablet should be swallowed whole with plenty of water.

- Paracetamol is not suitable for children below 10 years.
- Between two intakes should be at least 4 hours.
 - Do not use in combination with other Paracetamol-containing preparations.
 - Do not exceed the stated dose.
 - Paracetamol scored for easy breaking for use in Children.
 - If the pain persists for more than 5 days or the fever lasts for more than 3 days exists or gets worse or other symptoms appear, you should stop the treatment and consult a doctor.

The maximum daily dose should not exceed 60 mg/ kg/ day (up to 2 g/ day) in the following situations:

- adults weighing less than 50 kg
- mild to moderate hepatic insufficiency, Gilbert's syndrome (familial non-hemolytic jaundice)
- dehydration
- chronic malnutrition

Follow these instructions unless your doctor has given you different advice.

If you feel that Paracetamol too strong or too weak, talk to your doctor or pharmacist.

Method of administration:

Swallow the tablet with a glass of water.

If you take more Paracetamol than you should:

SEEK IMMEDIATE MEDICAL ADVICE IN THE EVENT OF AN OVERDOSE, EVEN IF YOU FEEL WELL, because of the risk of **delayed, serious liver damage**. Symptoms of Paracetamol overdose are nausea, vomiting and reduced appetite. Unconsciousness does not usually occur.

If you forget to take Paracetamol:

Do not take a double dose to make up for a forgotten tablet. Instead you should simply continue with the next dose when it is due.

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

4. Possible side effects

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

Possible side effects are listed below and classified as:

Rare side effects (may affect up to 1 in 1,000 people)

- Several blood disorders including agranulocytosis, thrombocytopenia, thrombocytopenic purpura, hemolytic anemia leukopenia platelet disorders (clotting disorders) and stem cell disorders (disorders of the blood forming cells in bone marrow).
- Allergic reactions.
- Depression, confusion, hallucinations.
- Tremor, headache.
- Disturbed vision.
- Oedema (abnormal accumulation of fluid under the skin).
- Abdominal pain, stomach or intestinal bleeding, diarrhoea, nausea, vomiting.
- Abnormal liver function, liver failure, jaundice (with symptoms like yellowing of the skin and eyes), hepatic necrosis (death of liver cells).
- Rash, itching, sweating, hives, red patches on skin, angioedema with symptoms like swollen face, lips, throat or tongue.
- Dizziness, generally feeling unwell (malaise), fever, sedation, interactions with medicines.
- Overdose and poisoning.

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

- Pancytopenia (reduction in the number of blood cells).
- Allergic reactions where treatment should be stopped, including angioedema, difficulty breathing, sweating, nausea, hypotension, shock, and anaphylaxis.
- Low level of blood glucose in the blood.
- Hepatotoxicity (damage caused to the liver due to chemicals).
- Cloudy urine and kidney disorders.
- Bronchospasm (difficulty in breathing) in patients sensitive to aspirin and other anti-inflammatory medicines
- Hematuria (blood in urine).
- Enuresis (inability to urinate).

Not Known (frequency cannot be estimated from the available data):

- Acute generalized exanthemateus pustulosis (drug eruption characterized by numerous small, primarily non-follicular, sterile pustules).
- Severe skin rash or peeling of the skin.
- Stevens–Johnson syndrome (a severe life-threatening skin disorder).
- Reddening of skin, blisters or rash due to intake of paracetamol.

Once you stop taking the medicine these side effects should go away. If any of the side effects gets serious, please tell 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. 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.

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.

This medicinal product 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 contains

- The active substance is paracetamol. Each tablet contains 500 mg paracetamol.
- The other ingredients are: Pregalatinized starch (maize), silica colloidal anhydrous, hydroxypropylcellulose (low viscosity grade), sodium starch glycolate (type-A), talc, magnesium stearate.

What Paracetamol looks like and contents of the pack

Tablet.
White to off-white, uncoated, round shaped tablets debossed with 'A' and '8' separated with break line on one side and plain on other side. The tablet can be divided into equal doses.

Paracetamol 500mg tablets are available in white opaque PVC-child resistant PVC backed aluminium foil blister packs.

Paracetamol tablets are available in blister packs of 16, 20, 30, 40 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

Manufacturer

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

or

Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

or

Generis Farmacêutica, S.A., Rua
João de Deus, 19, 2700-487
Amadora, Portugal

This leaflet was last revised in 05/2023.

P15XXXXX