

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

<Invented Name> Paracetamol

For OTC medicinal products

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 or nurse 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 or nurse. 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.

For prescription only medicine

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 or nurse.
- 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 <Invented Name> is and what it is used for
2. What you need to know before you take <Invented Name>
3. How to take <Invented Name>
4. Possible side effects
5. How to store <Invented Name>
6. Contents of the pack and other information

1. What <Invented Name> is and what it is used for

<Invented Name> contains active substance paracetamol which belongs to a group of medicines called analgesics (painkillers).

<Invented Name> is used to relieve pain and help reduce fever. The tablets can treat mild to moderate pain and/or fever.

<Invented Name> may be used in adults and adolescents but is not suitable for use in children below 6 years.

2. What you need to know before you take <Invented Name>

Do not take <Invented Name>:

- If you are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6).
- If you are below 6 years of age.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking <Invented Name>

- if you are taking other paracetamol containing medicines, as it may severely damage the liver.
- 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 haemolytic anaemia (abnormal breakdown of red blood cells).
- if you regularly take large amounts of alcohol. Never take more than 4 tablets a day.
- if you are asthmatic sensitive to acetylsalicylic acid.
- in case of dehydration or chronic malnutrition

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.

Children and adolescents

<Invented Name> should not be given to children under 6 years. .

Other medicines and <Invented Name>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Do not use <Invented Name> 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)
- cholestyramine (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)
- probenecide (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)

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.

<Invented Name> with food and drink and alcohol

It is advised not to drink large amounts of alcohol when taking <Invented Name>

Pregnancy and breast-feeding and fertility

Pregnancy

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

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

Breast-feeding

Although paracetamol is excreted in the breast milk in small amounts it has no unwanted effects on the child that is breast fed. Paracetamol may be used by breastfeeding women as long as the recommended dosage is not exceeded. In case of long term use caution should be exercised.

Fertility

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

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

Driving and using machines

<Invented Name> is not expected to impair your ability to drive or to operate machinery.

3. How to take <Invented Name>

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

The recommended dose is:

Adults and children over 15 years (> 55 kg body weight):

1 to 2 tablets (500-1000 mg) at a time, if necessary, repeat every 4 to 6 hours, up to 6 tablets (3000 mg) per 24 hours.

Children aged 6 to 9 years (22-30 kg body weight):

Half tablet at a time, up to 4 to 6 times per 24 hours.

Children aged 9 to 12 years (30-40 kg body weight):

One tablet at a time, up to 3 to 4 times per 24 hours.

Children 12 to 15 years (40-55 kg body weight):

One tablet at a time (500 mg), maximum 4-6 times per 24 hours.

The least number of administrations per day is intended for the younger children in a particular group.

The tablet should be swallowed whole with plenty of water. Optionally, the tablet into a large amount of water to disintegrate, stir well and drink.

- <Invented Name> is not suitable for children below 6 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.
- If your symptoms of pain and/or fever return, you may repeat the treatment with <Invented Name >.
- <Invented Name> 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 effective 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-haemolytic jaundice)
- dehydration
- chronic malnutrition

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

If you feel that <Invented Name> too strong or too weak, talk to your doctor or pharmacist.

Method of administration:

Swallow the tablet with a glass of water or if desired, leave the tablet to dissolve in a glass of water and stir well before drinking.

If you take more <Invented Name> 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 <Invented Name>:

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 stop taking <Invented Name>

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

4. Possible side effects

Like all medicines, <Invented Name> can cause side effects, although not everybody gets them.

Possible side effects are listed below and classified as:

Rare side effects (affects 1 to 10 users in 10,000)

- 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 (affects less than 1 user in 10,000):

- 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.
- Haematuria (blood in urine).
- Anuresis (inability to urinate).

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

- Acute generalised exanthemateous 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 or nurse. 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](#)

5. How to store <Invented Name>

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date stated on the carton or container after "EXP." The expiry date refers to the last day of that month.
- This medicinal product does not require any special temperature 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 to protect the environment.

6. Contents of the pack and other information

What <Invented Name> contains

- The active substance is paracetamol. Each tablet contains 500 mg paracetamol.
- The other ingredients are: Maize Starch, Gelatin (E441), Silica, Colloidal Anhydrous (E551), Talc (E553B), Sodium Starch Glycolate (Type A) (E468) and Magnesium Stearate (E572).

What <Invented Name> looks like and contents of the pack

<Invented Name> are White, uncoated capsule shape tablet marked with "B score T" on one side and plain on the other side. The tablet can be divided into equal doses.

Dimension: Length, width and thickness of the tablet is 16.50±0.20 mm, 8.20±0.20 mm and 5.10±0.30 mm respectively.

<Invented Name> is packed in ALU-PVC blister packs.

Country wise legal status and pack size of <Invented Name> is provided in following pages.

Country	Legal Status		Pack size
	OTC	POM	
NL	✓	--	20, 50
BG	✓	--	20
CY	--	✓	56, 60
EE	✓	--	10,20, 100
FI	✓	✓	OTC: 10, 30 POM: 100, 300
FR	--	✓	16 Hospital Pack: 100, 300
IE	✓	--	24

LT	✓	--	10, 12, 20, 100
LV	✓	--	10, 20
MT	✓	✓	OTC: 16 POM: 32,100
AT	✓	✓	OTC: 10, 20 POM: 30, 60

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<To be completed nationally>

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

Country	Invented Name
AT	Paracetamol Accord 500 mg tabletten
BG	Paracetamol Accord 500 mg tablets
CY	Paracetamol Accord 500 mg tablets
EE	Paracetamol Accord
FI	Paracetamol Accord 500 mg tabletti
FR	Paracetamol Accord 500 mg comprimé
IE	Paracetamol 500 mg tablets
LV	Paracetamol Accord 500 mg tabletes
LT	Paracetamol Accord 500 mg tabletės
MT	Paracetamol 500 mg tablets
NL	Paracetamol Accord 500 mg tabletten

The leaflet was last approved in {MM/YYYY}.

< To be completed nationally >