PACKAGE LEAFLET

Package leaflet: Information for the patient

Paracetamol Accord 500 mg effervescent tablets
paracetamol

[For medicines available only on prescription:]
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 pharmacis.
- 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.

[For medicines available without prescription:]
Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
This medicine is available without prescription. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist 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. 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 <Invented Name> is and what it is used for

[For medicines available only on prescription:]
<Invented Name> contains paracetamol which belongs to the group of medicines called analgesics and antipyretics. <Invented Name> is used to relieve mild to moderate pain and/or fever.

[For medicines available without prescription:]
<Invented Name> contains paracetamol which belongs to the group of medicines called analgesics and antipyretics. <Invented Name> is used to relieve mild to moderate pain and/or fever i.e. fever in colds, headache, toothache, period pain, muscle and joint pain.
<To be completed nationally>

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).

-

Warnings and precautions
Talk to your doctor or pharmacist before taking <Invented Name>

- If you have liver problems.
- If you have asthma and at the same time are sensitive to acetylsalicylic acid.
- If you have Gilbert's syndrome (mild jaundice).
- If you are suffering from kidney problems .
- If you are suffering from glucose-6-phosphatedehydrogenase deficiency (enzyme deficiency).
- If you have severe liver insufficiency.
- If you have haemolytic anaemia (abnormal breakdown of red blood cells).
- If you use any other medicines affecting live function (see section other medicines and <Invented Name>).
- If you are malnourished or dehydrated.

During treatment with <product name>, tell your doctor straight away if:
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).

Do not use <Invented Name> if you have alcohol-related problems or liver damage and do not use <Invented Name> together with alcohol.

Do not take any other paracetamol containing products.

Do not take more <Invented Name> than the dose recommended in section 3 or that your doctor has prescribed.
Higher doses than the recommended doses **do not** provide better pain relief but instead increase the risk of very severe liver damage. Symptoms of liver damage will normally occur after a few days. Therefore it is important that you contact your doctor as soon as possible if you have taken more than the recommended dose.

Laboratory Tests
These tablets may affect the results of laboratory blood uric acid test and blood sugar level tests. Check with your doctor before the tests.

Other medicines and <Invented Name>
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

<Invented Name> can affect or be affected by other medicinal products. Tell your doctor or pharmacist if you are taking.

- Metoclopramide (used to treat nausea and vomiting)
- Warfarin (used to thin the blood). There is a risk that the effect of warfarin will be increased
- Probenecid (used for gout)
- Phenytoin, phenobarbital, or carbamazepine (used to treat epilepsy)
- Rifampicin (used to treat tuberculosis)
- Cholestyramine (used to treat dyslipidemia). This medicine should be taken at least one hour before or after taking paracetamol
- Chloramphenicol for injection (used to treat bacterial infections). However, chloramphenicol used to treat infections of the eye and <Invented Name> can be used together

- Zidovudine (a medicine used to treat HIV infection)
- St John's Wort extract (included in some herbal remedies)

flucloxacillin (antiobitic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

<Invented Name> with food and alcohol

Do not drink alcohol while you are taking <Invented Name>

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 or pharmacist for advice before taking this medicine.

If necessary, <Invented Name> can be used in pregnancy. However you should use the lowest effective 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.

<Invented Name> passes into breast milk, but is unlikely to affect breast-fed babies. However consult your doctor or pharmacist if you are taking paracetamol for a long period while breast-feeding.

Driving and using machines

<Invented Name> does not affect your ability to drive or use machines.

<Invented Name> contains sodium and sorbitol

Talk to your doctor or pharmacist if you need one or more effervescent tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.This medicine contains 418.5mg of sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 20.9% of the recommended maximum daily dietary intake of 2 g of sodium for an adult and is considered to represent 'high' sodium.

This medicine contains 100 mg sorbitol (E420) in each effervescent tablet. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

3. How to take <Invented Name>

[For medicines available only on prescription:]
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

[For medicines available without prescription:]
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.

The recommended dose is:
Adults and adolescents over 50 kg bodyweight (over 15 years):
1-2 tablets (500 mg-1 g) every 4 to 6 hours as required.
It is generally not required to exceed 3 g of paracetamol per day (6 tablets per 24 hours).
The maximum dose is 8 tablets (4 gram) in 24 hours.

Children:

Paediatric dosage should be based on body weight and suitable dosage form used.
Information on the age of the children within each weight group given below is for guidance only.

Children over 40 kg bodyweight (over 12 years): 1 tablet (500 mg) every 4-6 hours, 3 to 4 times per 24 hours. The maximum dose is 5 tablets (2.5 gram) in 24 hours. The dose interval should always be at least 4 hours.

[For medicines available without prescription:] You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

Maximum daily dose should not be exceeded due to risk of serious liver damage.

If you have severe kidney or liver problems, the dose should be reduced or the interval between doses should be prolonged. Ask your doctor for advice.

Method of administration
For oral administration. The tablets should be placed in a glas of water and allowed to dissolve completely before swallowing.

If you take more <Invented Name> than you should
Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much <Invented Name> can cause delayed, serious liver damage.

If you forget to take <Invented Name>
Do not take a double dose to make up for a forgotten dose.

If you have any questions on 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.

Stop taking <Invented Name> and contact a doctor or go to nearest hospital immediately if you experience any of these serious side effects:

- swollen face, tongue or throat, difficulty swallowing, hives and difficulty in breathing (angioedema) (rare side effect)
- severe allergic reaction or hypersensitivity reaction with fever, rash, swelling and sometimes fall in blood pressure (very rare side effect)
- serious skin reactions (toxic epidermal necrolysis and Stevens-Johnson's syndrome) (Frequency cannot be estimated from the available data)
- in rare cases <Invented Name> may affect the white blood cells to the detriment of the immune system. If you develop an infection with symptoms such as fever coupled with a severely deteriorated general state of health or a fever with local infection symptoms such as sore throat/mouth or difficulty urinating, you are to contact a doctor immediately so blood samples can be used to rule out a lack of white blood cells (agranulocytosis). It is important that you in connection with this inform medical personnel about your medication.

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

- oedema (abnormal accumulation of fluid under the skin)
- depression, confusion, hallucination, abnormal vision
- headache, tremor
- abdominal pain, diarrhoea, stomach or intestinal bleeding, nausea, vomiting
- abnormal liver function, liver failure, hepatic necrosis(death of liver cells), jaundice
- reduction of certain blood cells (red blood cells, platelets, and neutrophils), clotting disorders, stem cell disorders (disorders of the blood-forming cell in the bone marrow), haemolytic anaemia (abnormal breakdown of red blood cells)

- fever, sedation and sweating.

Very rare (may affect up to 1 in 10,000 people):
- serious breathing difficulties with shortness of breath
- liver damage
- low blood sugar levels
- cloudy urine, kidney disorders
- serious skin reactions
- dizziness (excluding vertigo), malaise.

Not known (frequency cannot be estimated from the available data):
- *erythema multiforme* (allergic reaction or infection of skin)
- accumulation of fluid on the larynx (voice box)
- anaemia (decrease in amount of red blood cells)
- kidney disorders (severe renal impairment, interstitial nephritis, blood in urine, inability to urinate)
- liver disorders and infection of the liver (hepatitis)
- vertigo.
- 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 orpharmacist. 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.* By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented Name>

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

Store below 30ºC.
Tube: Keep the tube tightly closed to protect from moisture.
Strip: Store in the original primary container to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration, like brown or black spots on the tablets, bulging of tablets or discoloration 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 <Invented Name> contains
The active substance(s) is paracetamol. Each tablet contains 500 mg paracetamol.

The other ingredients are: Anhydrous citric acid (E330), sodium hydrogen carbonate, sorbitol (E420), sodium carbonate anhydrous, povidone, simethicone, saccharin sodium, powdarome lemon premium (flavouring preparations, flavouring substances, natural flavouring substances, maize maltodextrin, acacia gum, alpha-tocopherol), macrogol.

What <Invented Name> looks like and contents of the pack
<Invented Name> 500 mg is white to off-white, round, flat, beveled edges tablets, plain on both sides with odour of lemon.

<Invented Name> is packed in perforated unit dose Strip [4 layer-Paper/PE/Alu/ Surlyn (co-polymer of Ethylene/Methacrylic acid/Zinc material)] and Tablet container with white opaque tamper evident polyethylene cap with inbuilt desiccant packs.
Pack sizes: 6, 10, 12, 16, 20, 24, 30, 40, 60, 90, 100 and 500 tablets.

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	**Member states**
Belgium	Paracetamol ParaCare 500 mg comprimés effervescents
Spain	Paracetamol Accord 500 mg Comprimidos Efervescentes EFG
France	Paracetamol Accord 500 mg comprimé effervescent
Romania	Paracetamol Accord 500 mg comprimate efervescente
Sweden	Paracetamol Accord 500 mg brustabletter

This leaflet was last revised in 20 November 2025.