

Package leaflet: information for the patient

Paracetamol Banner 500 mg soft capsules

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 have 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 Paracetamol Banner is and what it is used for
2. What you need to know before you take Paracetamol Banner
3. How to take Paracetamol Banner
4. Possible side effects
5. How to store Paracetamol Banner
6. Contents of the pack and other information

1. What Paracetamol Banner is and what it is used for

Paracetamol Banner contains 500 mg of paracetamol which belongs to a group of medicines named analgesics (painkillers).

Paracetamol Banner is used for symptomatic treatment of mild to moderate pain and/or fever.

Paracetamol Banner is indicated in adults and children weighing more than 30 kg (approximately above 9 years of age).

2. What you need to know before you take Paracetamol Banner

Do not take Paracetamol Banner if you:

- have ever had an allergic reaction to paracetamol or to any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor or pharmacist before taking Paracetamol Banner:

- liver or kidney disorder
- moderate to severe renal insufficiency (unsatisfactory activity of kidneys)
- mild to severe hepatic insufficiency (unsatisfactory activity of the liver)
- Gilbert's syndrome
- glucose-6-phosphate dehydrogenase deficiency
- haemolytic anaemia
- dehydration
- chronic nutritional problems (malnutrition)
- asthmatic patients who are sensitive to aspirin (= acetylsalicylic acid)
- if you use large quantities of alcohol every day; if this is the case, there is more risk of the occurrence of harmful effects on the liver
- if you are already taking other medicines containing paracetamol, do not take Paracetamol Banner
- if you are allergic to peanut or soya; you should not use this medicinal product.
- if your symptoms last for longer than 3 days or return, please contact your doctor.

Long-term or frequent use is not advised.

Consult your doctor if one of the above warnings applies to you or has applied to you in the past.

Children and adolescents

Do not give this medicine to children under 9 years because the potential benefits are not greater than the risks.

Other medicines and Paracetamol Banner

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This also applies to medicines which you are able to obtain on prescription.

Different medicines can influence each other.

Contact your doctor or pharmacist before you use paracetamol. In the event that you use one of the following medicines:

- barbiturates (a group of hypnotics and anaesthetics)
- certain antidepressants
- probenecid (an anti-jaundice medicine)
- chloramphenicol (an antibiotic)
- metoclopramide or domperidone (anti-nausea and anti-emetic medicines)
- cholestyramine (an anticholinergic)
- warfarin and other coumarins (anticoagulants)
- zidovudine (a medicine used for the treatment of AIDS)
- salicylamide (an analgesic)
- isoniazid (an anti-tuberculosis medicine)
- lamotrigine (an anti-epileptic medicine)

Paracetamol can influence the test results of different laboratory tests.

Please inform your doctor or pharmacist if you are taking 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.

Paracetamol Banner with food, drink and alcohol

With chronic alcohol abuse, the dose of paracetamol may not be higher than 2 grams (4 capsules) a day. The long-term use of paracetamol in combination with alcohol is likely to cause hepatic damage with paracetamol overdose.

Do not drink alcohol whilst taking Paracetamol Banner.

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.

Pregnancy

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

Breast-feeding

Although paracetamol is excreted in small quantities in the maternal milk, it does not have any adverse effect on children who are breastfed. Paracetamol can be used in the recommended dose for a short time by women who breastfeed.

Fertility

There is insufficient data available to indicate paracetamol has any effect on fertility.

Driving and using machines

As far as is known, paracetamol does not have any effect on the ability to drive or use machines.

Paracetamol Banner contains sorbitol

This medicine contains sorbitol.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Paracetamol Banner contains propylene glycol

This medicine contains propylene glycol.

Paracetamol Banner contains lecithin originating from soya oil

If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take Paracetamol Banner

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 older than 15 years (> 55 kg body weight):

Take 1 to 2 capsules (500 - 1,000 mg) at a time, with a maximum of 6 capsules (3000 mg) every 24 hours.

Children weighing less than 30 kg (approximately below 9 years old):

Do not give to children under 9 years. For children under 9 years, other formulations and dosage strengths are available which may be more appropriate.

Children and adolescents weighing between 31 and 55 kg (approximately from 9 to 15 years old):

- For children weighing 31 to 40 kg (approximately 9 to 12 years): take 1 capsule (500 mg) at a time, with a maximum of 4 capsules (2000 mg) per day.
- For children weighing 41 to 55 kg (approximately 12 to 15 years): take 1 capsule (500 mg) at a time, with a maximum of 6 capsules (3000 mg) per day.

The lower frequency of administration is intended for the youngest children in the relevant age group. For children weighing less than 50 kg (approximately below 12 years of age) the daily dose should not be higher than 60 mg/kg body weight.

Method of administration

The capsules should be taken orally.

Duration of treatment

- There must be at least 4 hours between two intakes.
- Do not use in combination with other paracetamol-containing products.
- Do not exceed the stated dose.
- If the symptoms of pain and/or fever recur, administration can be repeated on the basis of the stated dosage regimen.
- If pain lasts for longer than 5 days or fever lasts for longer than 3 days or these symptoms become worse or if other symptoms occur, the treatment must be stopped and a doctor must be consulted.

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

- adults who weigh 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 other advice.

If you notice that this drug has too strong or too little effect, consult your doctor or pharmacist.

If you take more Paracetamol Banner than you should

Talk to a doctor at once if you take too much of this medicine, even if you feel well.

When a higher dose than that stated is taken, nausea, vomiting and a lack of appetite can occur. The taking of several times the maximum daily dose at once can cause very severe hepatic damage. A loss of consciousness does not usually occur. Nevertheless, you should usually seek immediate medical help.

If you do not act in time, the damage to the liver might be irreversible.

If you forget to take Paracetamol Banner

Do not give/take a double dose to make up for a forgotten dose.

If you stop taking Paracetamol Banner

If you suddenly stop taking Paracetamol Banner, nothing in particular will occur

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.

Side effects which may occur are:

Rare (1 in 10,000 to 1 in 1,000 users)

- different blood abnormalities, including agranulocytosis, thrombopenia, thrombocytopenic purpura, leukopenia and hemolytic anemia
- allergies (exclusive of angioedema)
- abnormal hepatic function, hepatic failure, hepatic necrosis and jaundice
- itching (pruritus), rash, perspiration, purpura and nettle rash/hives (urticaria)
- overdose and intoxication
- depression, confusion and hallucinations
- tremor and headache
- blurred vision
- oedema
- bleeding, gastric pain, diarrhoea, nausea, vomiting
- dizziness, fever and somnolence

Very rare (affects less than 1 user in 10,000)

- pancytopenia (reduction in the number of blood cells)
- hypersensitivity reactions as a result of which treatment must be stopped, including angioedema, breathing difficulties, perspiration, nausea, hypotension, shock and anaphylaxis
- feeling of tightness in the chest as a result of cramp of the respiratory muscles (bronchospasm)
- in people who are sensitive to aspirin and other NSAIDs (group of analgesics with anti-inflammatory and antipyretic activity).
- hepatic intoxication
- rash (exanthema)
- hypoglycemia (too low blood sugar level)
- dark urine (sterile pyuria) and renal reactions
- severe cutaneous reactions

Not known (cannot be determined with the available data):

- acute generalised exanthematous pustulosis, toxic necrolysis, drug-induced dermatosis and Stevens-Johnson syndrome.

After the long-term use of 3 to 4 grams of paracetamol per day, hepatic damage is possible. Hepatic damage is also possible after the use of 6 grams of paracetamol at once.

If you experience a side effect which is not mentioned in this package insert or which you consider to be serious, inform 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Paracetamol Banner

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

Do not store above 25°C. Store in the original package in order to protect from moisture.

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

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 Banner contains

- The active substance is paracetamol. One capsule contains 500 mg paracetamol.
- The other ingredients (excipients) are macrogol, purified water, propylene glycol, povidone, silica, colloidal anhydrous, gelatin, sorbitol, liquid, partially dehydrated, glycerol, titanium dioxide (E171).

What Paracetamol Banner looks like and contents of the pack

- Paracetamol Banner is a white, oblong soft gelatin capsule.
- Paracetamol Banner is supplied in a PVDC/PVC//Alu/PET blister. Each pack contains 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30 or 32 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Patheon Softgels B.V. (trading as Banner Pharmacaps Europe)

De Posthoornstraat 7

5048 AS Tilburg

The Netherlands

Manufacturer

Patheon Softgels B.V.

De Posthoornstraat 7

5048 AS Tilburg

The Netherlands

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

Netherlands: Paracetamol Banner 500 mg, zachte capsules

Ireland: Paracetamol Banner 500 mg, soft capsules

United Kingdom: Paracetamol 500 mg, capsules, soft

This leaflet was last revised in September 2022.