Package leaflet: Information for the user

Paracetamol 500 mg Film-coated 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 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 effect, 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 is and what it is used for

Paracetamol contains paracetamol which belongs to a group of medicines called analgesics (painkillers).
Paracetamol is used to relieve mild to moderate pain and reduce fever.
Paracetamol can be used for the relief of headache, toothache, period pains, muscle pain and fever in connection with common cold.

Paracetamol "Contains PARACETAMOL"

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
Paracetamol should not be used in combination with alcohol, as it may severely damage your liver. The effect of alcohol will not be enhanced by the addition of paracetamol.

Talk to your doctor before taking Paracetamol:
- if you have kidney or liver disease (including Gilbert's syndrome or hepatitis);
- if you regularly consume large amount of alcohol. You may need lower doses and to limit the use for a short period of time, otherwise your liver may be affected;
- if you are dehydrated or have impaired nutritional state e.g. caused by alcohol abuse, anorexia or wrong nutrition;
- if you have haemolytic anaemia (abnormal breakdown of red blood cells);
- if you have a deficiency of a certain enzyme called glucose- 6-phosphatedehydrogenase;
- if you are using other medicines that are known to affect the liver;
- if you are using other paracetamol containing medicines, as it may severely damage the liver;
- if you are using pain relieving medicines frequently for a long period of time, as prolonged use may cause more severe or more frequent headache. You should not increase your dose of the pain relieving medicine, but contact your doctor for advice;
- if you are asthmatic and sensitive to acetylsalicylic acid
- if you have a serious infection such as blood poisoning, as this may increase the risk of so called metabolic acidosis. Signs of metabolic acidosis include: deep, fast, strained breathing; nausea, vomiting; loss of appetite. Contact a doctor immediately if you get a combination of these symptoms.

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Warning: Ingestion of higher doses than the recommended involves risk of serious liver damage. The maximal daily dose of paracetamol must therefore **not** be exceeded. Care should also be taken for concurrent use of other medicinal products also containing paracetamol. See also section 3 "If you take more Paracetamol than you should".

In case of high fever or signs of infection after more than 3 days of treatment or if pain persists after more than 5 days of treatment, you should contact your doctor.

Other medicines and Paracetamol
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important in case of:
- **chloramphenicol** (to treat infections), as Paracetamol may delay its removal from the body;
- **metoclopramide** or **domperidone** (to treat nausea and vomiting) as it may increase the onset of effect of Paracetamol;
- **colestyramine** (to lower cholesterol) and **medicines that slow emptying of the stomach**, as they can weaken the effect of Paracetamol;
- **probenecid** (to treat e.g. gout). You may need lower doses of Paracetamol;
- **anti-coagulants** (drugs to thin the blood, e.g. **warfarin**), in case you need to take Paracetamol on a daily basis over a long period;
- **salicylamide** (to treat fever or mild pain), as it may delay removal of Paracetamol from the body;
- **lamotrigine** (to treat epilepsy), as Paracetamol may reduce its effects;
- Possibly liver-damaging medicines such as:
  - **barbiturates** or **carbamazepine** (to treat mental disorders and epilepsy);
  - **rifampicin** (to treat bacterial infections);
  - **isoniazid** (to treat tuberculosis);
  - **phenytoin** (to treat epilepsy);
  - **St John's wort** (*Hypericum perforatum*) (to treat depression).

Do NOT take any other paracetamol-containing products

Paracetamol can affect how some laboratory tests work, such as tests for uric acid and blood sugar.

Paracetamol with alcohol
Concurrent use of Paracetamol and consumption of alcohol should be avoided.

Pregnancy and breast-feeding
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. 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.

Paracetamol in recommended doses may be used during breast-feeding.

Driving and using machines
Paracetamol does not influence your ability to drive or use machines.

3 How to take Paracetamol

Instructions for use
The tablet should be swallowed with a glass of water.

Dosage
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Do not exceed the stated dose. Please observe that higher doses than those recommended may result in a risk of very serious liver damage.

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

Adults and adolescents weighing more than 50 kg
The usual dose is 1 to 2 tablets (500 mg to 1,000 mg) every 4 to 6 hours as needed, to a maximum of 6 tablets (3 g) daily.

Children and adolescents weighing 43-50 kg (about 12-15 years)
The usual dose is 1 tablet (500 mg) every 4 hours as needed, to a maximum of 5 tablets (2.5 g) daily.

Children weighing 34-43 kg (about 11-12 years)
The usual dose is 1 tablet (500 mg) every 6 hours as needed, to a maximum of 4 tablets (2 g) daily.

Children weighing 26-34 kg (about 8-11 years)
The usual dose is ½ of one tablet (250 mg) every 4 hours or 1 tablet (500 mg) every 6 hours as needed, to a maximum of 3 tablets (1.5 g) daily

Paracetamol 500 mg is not intended for children weighing less than 26 kg.

In case of high fever or signs of infection after more than 3 days of treatment or if pain persists after more than 5 days of treatment, you should contact your doctor.

Patients with impaired kidney or liver function
In patients with impaired kidney or liver function and patients with Gilbert´s syndrome, the dose has to be reduced or the dosing interval prolonged. In patients with severely impaired kidney function the dosing interval of Paracetamol has to be at least 8 hours. Ask your doctor or pharmacist for advice.

Elderly patients
Dose adjustment is not required in the elderly.

Patients with chronic alcoholism
Chronic alcohol consumption can increase the risk of paracetamol toxicity. The length of time between two doses should be at least 8 hours. Do not exceed 2 g paracetamol daily.

If you take more Paracetamol than you should
Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious irreversible liver damage. To avoid possible liver damage it is important that an antidote is given by a doctor as soon as possible. Symptoms of liver damage normally do not appear until after a few days. Symptoms of overdose may include nausea, vomiting, anorexia (loss of appetite), paleness and abdominal pain and these symptoms usually occur within 24 hours after intake.

4 Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience difficulty in breathing, swelling of the face, lips, neck, tongue or throat (severe allergic reactions) **stop taking this medicine** and seek **immediate** medical advice.

Rare: may affect up to 1 in 1,000 people
- Blood platelet disorders (clotting disorders), 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.
- Dizziness, generally feeling unwell (malaise), fever, sedation, interactions with medicines.
- Overdose and poisoning.

Very rare: may affect up to 1 in 10,000 people:
- Blood disorders (reduction in platelets, white blood cells and neutrophils in the blood, haemolytic anaemia (abnormal breakdown of red blood cells)).
- Low level of blood glucose in the blood.
- Hepatotoxicity (damage caused to the liver due to chemicals).
- Cloudy urine and kidney disorders.

Very rare cases of serious skin reactions have been reported.

Not known: frequency cannot be estimated from the available data:
Erythema multiforme (allergic reaction or infection of skin), accumulation of fluid in the larynx, anaphylactic shock (severe allergic reaction), anaemia (decrease in red blood cells), liver alteration and hepatitis (liver inflammation), kidney alterations (severe kidney impairment, blood in urine, inability to urinate), disorder of stomach and intestine, vertigo.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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
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 light.

Do not use this medicine after the expiry date which is stated on the carton and blister after "EXP". 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 contains
- The active substance is paracetamol. Each film-coated tablet contains 500 mg paracetamol.
- The other ingredients are: *tablet core:* pregelatinised maize starch, hydroxypropylcellulose, talc and magnesium stearate; *film coating:* polyvinyl alcohol, macrogol 3350 and talc.

What Paracetamol looks like and contents of the pack
Capsule-shaped, white film-coated tablet, 17.0 mm x 7.2 mm, with break-line on one side.

The tablet can be divided into equal halves.

Pack sizes:
Blister packs: 10, 12, 20, 24 and 30 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Actavis Group PTC ehf
Reykjavikurvegi 76-78
220 Hafnarfjordur
Iceland.

Manufacturer
Balkanpharma – Dupnitsa AD
3, Samokovsko Shosse Str., 2600 Dupnitsa, Bulgaria

Or

Orifice Medical AB
Aktergatan 2, 4 och 5
271 55 Ystad
Sweden

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

Iceland	Sigamol
Austria	Paracetamol Actavis 500 mg Filmtabletten
Germany	Paracetamol apo-rot 500 mg Filmtabletten
Ireland	Paracetamol 500 mg film-coated tablets
Sweden	Paracetamol Actavis

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