

Paracetamol
500mg Film-coated tablets

The full name of this medicine as listed above has been abbreviated throughout the leaflet for ease of reference to 'paracetamol tablets' or 'paracetamol'.

Package Leaflet: Information for the user.

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 the leaflet or as your doctor or pharmacist 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4. You must see a doctor if your symptoms worsen or do not improve after 3 days**

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1. WHAT PARACETAMOL IS AND WHAT IT IS USED FOR

Each film-coated tablet contains paracetamol 500mg.

Paracetamol is an analgesic (relieves pain) and antipyretic (reduces high temperature).

Your medicine is for the treatment of the symptoms of mild to moderate pain such as, **headache, period pains, migraine, rheumatic aches, neuralgia (sharp nerve pain), toothache, symptoms of flu, feverishness, colds and sore throat.**

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARACETAMOL TABLETS

Please read the following information.

Do not give to children under 6 years of age.

Alternative liquid paracetamol formulations are available which may be more appropriate, especially for younger children. This medicine is not appropriate for children under 6 years of age.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium free". Do not take if you:

- are allergic to paracetamol, or any of the other ingredients listed in this leaflet.
- are taking any other paracetamol containing products

Take special care and talk to a pharmacist or your doctor before taking this medicine if you:

- are suffering from liver or kidney disease (including alcoholic liver disease).
- are suffering from chronic malnutrition and weigh less than 50 kg.
- are suffering from dehydration.
- are suffering from a condition which causes abnormal breakdown of red blood cells.
- are elderly.
- regularly drink alcohol.
- have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), suffer from malnutrition, chronic alcoholism or if you are taking flucloxacillin (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 is taken together with flucloxacillin. Symptoms may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Contact a doctor immediately if you get a combination of these symptoms.

Taking other medicines:

If you take blood thinning drugs (anticoagulants e. g. warfarin) and you need to take a pain reliever on a daily basis, talk to your doctor because of the risk of bleeding. However you can still take occasional doses of paracetamol tablets at the same time as anticoagulants. Talk to your doctor or pharmacist if you are taking some antibiotics (chloramphenicol), anti-sickness treatments (metoclopramide, domperidone), or lipid lowering drugs (cholestyramine).

Please inform your doctor or pharmacist if you are taking flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see Section 2).

Pregnancy and breast-feeding

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 or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often. Paracetamol can be taken when breastfeeding. Paracetamol can be found in breast milk in small amounts. Only take when clearly necessary. (See Section 3.)

Driving and using machines

Paracetamol is not known to affect driving or using machinery.

3. HOW TO TAKE PARACETAMOL TABLETS

For oral administration and short term use only.

Dosage:

Do not exceed the stated dose.

Only take when clearly necessary.

Prolonged use without medical supervision could be harmful.

If symptoms persist for more than 3 days or you experience any other symptoms not related to the original condition, discontinue treatment immediately and consult your doctor.

The minimum effective dose should be used for the shortest time necessary to relieve symptoms.

Adults, the elderly and young persons aged 16 and over:

Take one to two tablets every 4-6 hours as required. Do not take more than 8 tablets in 24 hours.

Children:

Alternative liquid paracetamol formulations are available which may be more appropriate, especially for younger children.

Do not give to children under 6 years of age.

For children 6 to 9 years of age: Give ½ a tablet with a drink of water, every 4 to 6 hours as required.

Do not give more than 4 doses in a 24-hour period.

For children 10 to 11 years of age:

Give 1 tablet with a drink of water, every 4 to 6 hours, as required. Do not give more than 4 doses in a 24-hour period.

Children, 6 to 11 years: Maximum duration of continued use without medical advice: 3 days.

For adolescents 12 to 15 years of age:

Give 1 to 1 ½ a tablet with a drink of water, every 4 to 6 hours as required. Do not give more than 4 doses in a 24-hour period.

If you take more tablets than you should:

If you take too many tablets, **IMMEDIATE** medical advice should be sought even if you feel well, because of the risk of irreversible liver damage. You may have no symptoms of overdose but the most

common symptoms of overdose are paleness of face, nausea, vomiting, loss of appetite, or stomach pain and these may not reflect the severity of overdose or the risk of organ damage.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **paracetamol** can cause side effects, although not everybody gets them. Very rare cases of serious skin reactions have been reported.

Stop taking this medicine and tell your doctor immediately if:

- You experience allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- You experience a skin rash or peeling, or mouth ulcers.
- You have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories and experience a similar reaction with this product.
- You experience unexpected bruising or bleeding.
- You experience liver dysfunction, this may include yellowing of the skin and eyes, pain in your upper right abdomen, swollen abdomen, nausea and vomiting.

You experience a serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

These reactions occur at a frequency that is not known as they cannot be estimated from the data available.

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 HPRC Pharmacovigilance, website: www.hpra.ie

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

5. HOW TO STORE PARACETAMOL TABLETS

- Do not use this medicine after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of the month.
- Do not store above 25°C.
- Keep out of the sight and reach of children.

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. CONTENT OF THE PACK AND OTHER INFORMATION

What does this medicine contain?

The active substance is paracetamol. Each tablet contains 500 mg of paracetamol. This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium free".

The other ingredients are: Croscarmellose sodium, povidone, pregelatinised maize starch, and stearic acid. The tablet coating contains hypromellose (E464) and macrogol.

What paracetamol tablets look like and contents of pack?

The tablets are white capsule shaped Film-coated tablets embossed on one face with " P-500" and with a break bar on the reverse. Paracetamol tablets are available in pack sizes of 6, 8, 12, 16, 24 and 32 tablets. Not all pack sizes may be marketed.

Who makes this medicine?

Manufacturer: Haleon Italy Manufacturing S.r.l., Via Nettunense 90, Aprilia, Italy.

Marketing Authorisation Holder: Haleon Ireland Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

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