

PACKAGE LEAFLET – INFORMATION FOR THE USER

PARACETAMOL 500MG CAPSULES

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

1. WHAT PARACETAMOL IS AND WHAT IT IS USED FOR

The name of your medicine is Paracetamol 500mg Capsules (called paracetamol throughout this leaflet). This medicine contains paracetamol. It belongs to a group of medicines called analgesics (painkillers) and is used for the treatment of headaches (including migraine and tension headaches), toothache, nerve pain, backache, muscle pain, joint pain, a sore throat and a period pain). It is also used to lower a high temperature and relieve the symptoms of cold or flu.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARACETAMOL

Do not take paracetamol and tell your doctor if:

- You are allergic to the active substance or any of the other ingredients in your medicine (listed in section 6) Signs of an allergic reaction include a rash and breathing problems. There can also be swelling of the legs, arms, face, throat or tongue

Children

Paracetamol 500mg Capsules must not be given to children under 10 years of age

Do not take paracetamol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking paracetamol.

Warnings and precautions

Take special care and check with your doctor before taking paracetamol if:

- You have severe kidney or liver problems
- You have a liver problem caused by alcohol

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

During treatment with paracetamol, 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).

Other medicines and paracetamol

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because paracetamol can affect the way some other medicines work. Also, some other medicines can affect the way paracetamol works.

While taking paracetamol you should not take any other medicines which contain paracetamol.

This includes some painkillers, cough and cold remedies. It also includes a wide range of other medicines available from your doctor and more widely in shops.

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).

Tell your doctor if you are taking any other medicines:

- Medicines used to thin the blood such as warfarin.
- Metoclopramide or domperidone – used to stop you feeling sick (nausea) or being sick (vomiting).
- Colestyramine – for lowering blood cholesterol levels.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking paracetamol.

Paracetamol with alcohol

You should not drink alcohol whilst taking these capsules. Taking paracetamol with alcohol can increase your chances of getting side effects.

Pregnancy and breast-feeding

Talk to your doctor before taking these capsules if:

- You are pregnant, think you may be pregnant or plan to get pregnant
- You are breast-feeding or planning to breast-feed

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.

Important information about some of the ingredients of Paracetamol

This medicine contains less than 1mmol sodium (23mg) per dose, that is to say essentially 'sodium free'

3. HOW TO TAKE PARACETAMOL

Always take paracetamol exactly your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Do not take more than the recommended dose
- If you need to use this medicine for more than three days at a time, see your doctor

Adults and children over 16

- The usual dose of paracetamol is 2 capsules
- Swallow the capsules whole with a drink of water
- Wait at least 4 hours before taking another dose
- Do not take more than 4 doses in any 24-hour period

Use in children aged 10 to 15 years

Take one capsule every four to six hours when necessary to a maximum of four doses in 24 hours.

Use in children under 10

Paracetamol 500mg Capsules should not be given to children under 10 years of age.

If you take more paracetamol 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 paracetamol can cause delayed, serious liver damage.
- Remember to take any remaining capsules and the pack with you. This is so the doctor knows what you have taken

If you forget to take paracetamol

If you forget to take a dose at the right time, take it as soon as you remember. However, do not take a double dose to make up for a forgotten dose. Remember to leave at least 4 hours between doses.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Stop taking paracetamol and see a doctor or go to a hospital straight away if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria)

This may mean you are having an **allergic reaction** to paracetamol

- You get serious skin reactions. Very rare cases have been reported.

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:

- You get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis, neutropenia or thrombocytopenia). This side effect has only happened in a few people taking paracetamol

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

- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 use this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.
- Store your medicine in the original packaging in order to protect from moisture.
- 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 500mg Capsules contain

- The active substance is paracetamol. Each capsule contains 500mg of paracetamol.

The other ingredients are: maize starch and magnesium stearate. The capsule is made of gelatine and sodium lauryl sulfate and is coloured with titanium dioxide (E171), erythrosine (E127), yellow iron oxide (E172) and indigo carmine (E132). The ink used to print on the capsules contains shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, sodium hydroxide, povidone and titanium dioxide.

What Paracetamol 500mg Capsules look like and contents of the pack

The capsules are blue and white in colour with "S174" printed in white ink on the capsule. It contains white powder.

Paracetamol 500mg Capsules come in cartons of 48, 60, 96 and 100 capsules. Not all pack sizes may be sold.

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