

PACKAGE LEAFLET – INFORMATION FOR THE USER

PARACETAMOL 500MG SOLUBLE TABLETS

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 pharmacist
- Do not pass this medicine 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 Soluble Tablets (called paracetamol throughout this leaflet). This medicine contains paracetamol. It belongs to a group of medicines called analgesics (painkillers) and is used to treat pain (including headache, toothache and period pain) and cold or flu symptoms.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARACETAMOL

Do not take paracetamol and tell your doctor if:

- You are allergic (hypersensitive) 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 Soluble Tablets 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.

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).

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.

Tell your doctor if you are taking any of the following 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 while you are taking these tablets. Taking alcohol with paracetamol can increase your chances of getting side effects.

Pregnancy and breast-feeding

Talk to your doctor before taking these tablets 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.

Paracetamol tablets contain:

- **Sodium:** This medicine contains 388 mg sodium (main component of cooking/table salt) in each soluble tablet. This is equivalent to 19.4 % of the recommended maximum daily dietary intake of sodium for an adult.
- **Sorbitol:** This medicine contains 50 mg sorbitol in each soluble 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 PARACETAMOL

Always take paracetamol exactly as it says in this leaflet. 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 effervescent tablets
- Dissolve the effervescent tablets in a full glass of water before taking
- Wait at least 4 hours before taking another dose
- Do not take more than 4 doses in any 24-hour period

Use in children

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

Children aged 10 to 15 years

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

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 tablets 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).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 store above 25°C.
- 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 Soluble Tablets contain

- The active substance is paracetamol. Each tablet contains 500mg of paracetamol.
- The other ingredients are sorbitol, saccharin sodium, sodium lauryl sulphate, citric acid, sodium carbonate, sodium bicarbonate, povidone, and dimeticone.

Contents of the pack

Paracetamol 500mg Soluble Tablets come in cartons of 12, 16, 24, 32, 48, 60 and 100. Not all pack sizes may be sold.

The Marketing Authorisation Holder is

Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, United Kingdom

The Manufacturer is

LAMP SAN PROSPERO SPA, VIA DELLA PACE 25/A, SAN PROSPERO (MO) 41030, Italy

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ZENTIVA

GENERAL INFO:

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PRODUCT NAME:	PIL COMON PARACETAMOL 500MG TABEF GB
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AW VERSION:	V4
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AW BY:	MiU
SUPPLIER:	LAMP

REASON OF REVISION:

Site transfer from cologne to CMO-Lamp; ZNtbc;

TECHNICAL INFO:

FORMAT (size):	180 x 430 mm
LAETUS (pharma code):	N/A
FONT + MIN. SIZE:	Helvetica Neue LT W1G 8.5 pt
MATERIAL TYPE (TS):	N/A

COLOURS: [1]

■ Black

TECH. COLOURS: [1]

■ DieCut

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