

PACKAGE LEAFLET – INFORMATION FOR THE USER

PARACETAMOL 500mg 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.

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 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, back 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 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 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.

Other medicines and paracetamol

Please 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 (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.

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.

Taking paracetamol with alcohol

You should not drink whilst 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.

3. HOW TO TAKE PARACETAMOL

Always take paracetamol exactly as instructed on 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 tablets
- Swallow the tablets 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

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

Use in children under 10

Paracetamol 500mg Tablets 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 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

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 Tablets contain**

- The active substance is paracetamol. Each tablet contains 500mg of paracetamol.
- The other ingredients are maize starch, purified talc, stearic acid, povidone, and soluble starch.

Contents of pack

Paracetamol 500mg Tablets come in cartons of 16, 32 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, UK

The Manufacturer is:

Zentiva Pharma UK Limited, Office 136-152, Austen House, Station View Units A-J, Guildford, GU1 4AR, UK.

or

Zentiva Pharma UK Limited, First floor, Andrews House, College Road, Guildford, GU1 4QB, United Kingdom.

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[940572]
ZEN-A-0209323-1-GB-EX
LEAFLET PARACETAMOL
500MG (UK) GB

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GENERAL INFO:

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AW BY:	Iulian Szidelo
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REASON OF REVISION:

Variation for Paracetamol 500 mg tbl (PL 17780/0069-0794-0808) IA/B.II.a.3.b.1) Change in the composition - to discontinue the use of preservative ζ potassium sorbate ζ from the manufacturing formula - Quantity of Potassium sorbate will be compensated by the use of Maize starch at intragranular stage ζ TRW 266632.

TECHNICAL INFO:

FORMAT (size):	140 x 240 mm (folded size 140 x 30 mm)
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■ Black

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artwork check list

Infobox check

PM code	(acc. Vista)	N/A
Product name	(acc. Vista)	N/A
SAP ID / GMID	(acc. Vista)	OK
Colors	(add only used colors)	OK

Technical check

Keyline	(acc. pack size/strength/dosage form)	OK
Inner safezones	(acc. keyline)	OK
Leatus code:	position and orientation	OK
	value of code	OK

Design check

Corresponds to:	leaflet design manual	OK
	registered mockup	OK
PM code placed on artwork	(acc. Vista)	OK
Color separations	(are colors used properly?)	OK
Logo placement	(check if proper logo is used)	OK

Legislation check

Font size	(minimum font size is 8.5 pt - Helvetica)	OK
Line spacing	(minimum line spacing is 8.5 pt)	N/A
Text according to:	QRD (text used acc. Vista)	OK
	Annotated PDF (acc. Vista)	N/A

New version check

V2

Update infobox	(version and other data if needed)	OK
Applied corrections	(check if only requested corrections have been applied)	OK

Leaflet	
Dimensions (L x H)	As per approved artwork
Paper grammage	40 g/m ² ± 5%
Thickness	0.06mm to 0.09 mm
Folds	Prefolded as per approved artwork (30x140 mm)
Text and Colour	As per approved artwork.
Type of Paper	Bible paper
Position of Pharmacode	Middle of folded leaflet(End to end folding of leaflet)
Nos of leaflets in supplied box	10000 nos.
qty of leaflet in bundle	100 nos.
Paper cover of bundles of leaflets	Blue

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