

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

PARACETAMOL 500MG TABLETS

(Paracetamol)

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.
- 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.

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1. WHAT PARACETAMOL 500MG TABLETS ARE AND WHAT THEY ARE USED FOR

Paracetamol 500mg Tablets contain the active ingredient paracetamol which belongs to group of medicines called analgesics. They are used for the relief of mild to moderate pain, including:

- rheumatic aches (joint pain) and pains
- neuralgia (severe nerve pain), period pain
- migraine, headache
- sore throat, toothache
- fevers, colds, flu and influenza.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARACETAMOL 500MG TABLETS

DO NOT take Paracetamol 500mg Tablets

- If you are allergic (hypersensitive) to Paracetamol, other pain relievers or any of the other ingredients in the product (*listed in section 6*)
- If you are taking any other or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.

This medicine is NOT recommended for children under 10 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Paracetamol 500mg Tablets:

- If you have kidney or liver problems
- If you are an alcoholic
- If you suffer from mild arthritis and need to take painkillers every day.
- If you are underweight or malnourished.
- If you have a severe infection as this may increase the risk of metabolic acidosis.

Signs of metabolic acidosis include:

- Deep, rapid, difficult breathing
- Feeling sick (nausea), being sick (vomiting)
- Loss of appetite

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

You may need to avoid using this product altogether or limit the amount of paracetamol that you take.

Other important warning:

If you are taking painkillers for headaches too often or for too long can make them worse

Other medicines and Paracetamol 500mg Tablets

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription, particularly:

- other products containing paracetamol (see '*DO NOT take Paracetamol 500mg Tablets*').
- warfarin and other drugs which thin the blood.
- cholestyramine (reduces blood cholesterol levels). Should not be taken at least one hour before and after taking paracetamol.
- metoclopramide and domperidone (used to treat nausea, vomiting or other stomach problems).

Paracetamol 500mg Tablets with food and drink

Avoid alcoholic drinks whilst taking these tablets.

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.

If necessary, Paracetamol 500mg Tablets 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.

Driving and using machines

Paracetamol 500mg Tablets are not expected to affect your ability to drive or operate machinery.

Paracetamol 500mg Tablets contains Sodium metabisulphite (E223)

Sodium Metabisulphite (E223) - may cause severe hypersensitivity reactions and bronchospasm (narrowing of airways in the lungs, causing difficulty in breathing). HWYUKP2

3. HOW TO TAKE PARACETAMOL 500mg TABLETS

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

Swallow each tablet with a drink of water.

The scoreline is not intended for breaking the tablet.

Adults, the elderly and children 16 years and over:

One or two tablets to be taken up to four times daily.

Maximum dose of 8 tablets in 24 hours.

Children 10 to 15 years of age: One tablet to be taken up to four times a day.

Children under 10 years of age: Not recommended.

Alternative presentations of paracetamol are recommended for paediatric usage in order to obtain suitable doses of less than 500mg.

The dose should not be repeated more frequently than every 4 hours and not more than 4 doses should be taken in any 24 hour period. You should not take Paracetamol 500mg Tablets for longer than 3 days.

WARNING: DO NOT EXCEED THE STATED DOSE
Contains paracetamol. Do not take with other
paracetamol containing products.

If symptoms persist consult your doctor. Do not use for more than 3 days without consulting your doctor.

If you take more Paracetamol 500mg Tablets than you should

It is extremely important to follow the dosage instructions that have been given to you. Do not change your dose without discussing it with your doctor first. Symptoms of overdose include pallor (paleness of skin), nausea, vomiting, anorexia (loss of appetite), feeling or being sick, liver damage and stomach pain. If you accidentally take more than the recommended dose, or know someone who has, contact your doctor or nearest hospital casualty immediately. Take any remaining medicine and this leaflet with you if possible.

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.

If you forget to take Paracetamol 500mg Tablets

If you miss a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Paracetamol 500mg Tablets can cause side effects, although not everybody gets them.

Stop taking this medicine and tell your doctor immediately if you experience following:

- Allergic reactions which may be severe such as skin rash, and itching sometime with swelling of the mouth or face or shortening of breath

- Skin rash or peeling or mouth ulcers
- Breathing problems. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin
- Unexplained bruising or bleeding
- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.

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 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 500MG TABLETS

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package.

Do not use this medicine after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Paracetamol 500mg Tablets contain

The **active** substance is paracetamol 500mg.

The **other** ingredients are maize starch, povidone K-30, sodium metabisulphite (E223), sodium starch glycolate, colloidal anhydrous silica and magnesium stearate (see *also end of Section 2 on 'Important information about some of the ingredients of Paracetamol Tablets'*).

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

The tablets are white, bisect on one side and plain on the other side.

Paracetamol are available in:

Paracetamol are available in 4, 8, 16, 24, 30 or 32 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

JCSH Pharma Ltd., Winslade, Shere Road, West Clandon, Surrey GU4 8SF, UK.

Manufacturer:

Sciecura Pharma Ltd., 5 Millmead, Guildford, Surrey GU2 4BE, UK.

Product License Number: PLGB 46447/0055

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