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Paracetamol 500mg Tablets (FPL) (GSL)

Leaflet Size : 255 x165 mm

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Package Leaflet: Information for the User

PARACETAMOL 500 MG TABLETS

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 this leaflet or as your doctor or pharmacist has 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or you feel worse after 3 days.

WHAT IS IN THIS LEAFLET

- What Paracetamol Tablets is and what it is used for
- What you need to know before you take Paracetamol Tablets
- How to take Paracetamol Tablets
- Possible side effects
- How to store Paracetamol Tablets
- Contents of the pack and other information

1. WHAT PARACETAMOL TABLET IS AND WHAT IT IS USED FOR

Each tablet contains 500 mg of the active ingredient Paracetamol. Paracetamol tablets belongs to a group of medicines called Analgesics and Antipyretics. Paracetamol tablets are used for the treatment of mild to moderate pain including headache, migraine, neuralgia (severe pain in nerves), toothache, period pains and the symptomatic relief of sprain, strain and rheumatic pains.

They also reduce temperature and used for the symptomatic relief of feverishness, feverish colds and influenza.

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

Do not take Paracetamol Tablets:

- if you are **allergic** to paracetamol or any of the other ingredients (listed in Section 6).
- if you are **taking any other prescription or non-prescription medicines that contain Paracetamol** to treat pain, fever, symptoms of cold and flu, or to aid sleep.

Ask your doctor before you take this medicine:

- if you suffer from **mild arthritis** and need to take painkillers every day.

- have **liver** or **kidney** problems
- are **underweight** or **malnourished**
- regularly drink alcohol
- 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 medicines and Paracetamol Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, particularly:

- Anticoagulant to **thin your blood** 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. But you can still take **occasional** doses of Paracetamol Tablets at the same time as anticoagulants.
- Medicines to control **nausea and vomiting** e.g. **Metoclopramide** or **domperidone**
- Medicines to lower **blood cholesterol** e.g. **Colestyramine**

Paracetamol Tablets with Alcohol

You are advised NOT to drink alcohol whilst taking Paracetamol tablets. Taking alcohol with Paracetamol can increase your chances of getting side effects.

Pregnancy and breast-feeding:

Talk to your healthcare professional before taking Paracetamol Tablets if you are **pregnant**. You can take this product whilst **breast feeding**.

Paracetamol Tablets contains Sodium Metabisulphite

Paracetamol Tablets contain sodium metabisulphite which may rarely cause severe hypersensitivity reactions and bronchospasm (breathing difficulties).

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

3. HOW TO TAKE PARACETAMOL TABLETS

Always take Paracetamol Tablets exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

For oral administration and short term use only. Swallow the tablets with water.

5. HOW TO STORE PARACETAMOL TABLETS

- This medicinal product does not require any special storage conditions.
- Do not use your tablets after the expiry date stated on the label or carton.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.
- These measures will help to protect the environment.
- Keep this medicine out of the sight and reach of children.**

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Paracetamol Tablets contains

These tablets contain 500 mg of Paracetamol as the active ingredient. They also contain pregelatinised starch, magnesium stearate (E572), stearic acid (E570) and sodium metabisulphite (E223).

What Paracetamol Tablets look like and contents of the pack.

Paracetamol Tablets are white to off white, circular flat bevelled edge tablet with break line on one side and plain on other. Paracetamol Tablets are available in blister packs of 4, 6, 12 and 16 Tablets.

Marketing Authorisation Holder
Flamingo Pharma (UK) Ltd.
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Manufacturer:
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If you would like this leaflet in different format information or want to report any side effects please contact marketing authorisation holder listed above.

This leaflet was last revised in October 2021.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Paracetamol can cause side effects, although not everybody gets them. A small number of people have had side effects. Very rare cases of serious skin reactions have been reported.

If you experience any of the following serious effects STOP taking this medicine immediately and contact your doctor or pharmacist:

- Allergic reactions** which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness 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 Google Play Store or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

Do not take more frequently than every 4 hours.

Do not take more than the recommended dose.

Do not give to children under 10 years.

Children aged 10-15 years:

Give 1 tablet every 4 to 6 hours as needed. Do not give more than 4 tablets in 24 hours. Do not give for more than 3 days at a time unless your doctor tells you to.

Adults and children aged 16 years and over:

Swallow 1-2 tablets every 4 to 6 hours as needed. Do not take more than 8 tablets in 24 hours.

Do not take more than 4 tablets in 24 hours.

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