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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.

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

1. What Paracetamol Tablets is and what it is used for
2. What you need to know before you take Paracetamol Tablets
3. How to take Paracetamol Tablets
4. Possible side effects
5. How to store Paracetamol Tablets
6. Contents of the pack and further information

1. WHAT PARACETAMOL TABLETS 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 medicines that contain Paracetamol

Take special care before taking Paracetamol Tablets:

- if you have severe kidney or liver problems including non-cirrhotic alcoholic liver disease
- if you have non-serious arthritis and need to take painkillers everyday

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 Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription.

- Chloramphenicol (an antibiotic): paracetamol may increase the levels of chloramphenicol in the blood
- Anticoagulant to thin your blood such e.g. warfarin
- Medicines to control nausea and vomiting e.g. Metoclopramide or domperidone
- Medicines to control high lipid levels e.g. Colestyramine

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).

Taking Paracetamol Tablets with alcohol

You should not drink alcohol whilst taking Paracetamol Tablets. Taking alcohol with paracetamol can increase your chances of getting side-effects

Pregnancy and breast-feeding:

If necessary, Paracetamol 500 mg 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.

Tell your doctor if you are pregnant or planning to become pregnant, or are breast-feeding. Ask your doctor or pharmacist for advice before taking any other medicine.

Paracetamol Tablets contains Sodium Metabisulphite.

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

3. HOW TO TAKE PARACETAMOL TABLETS

Always take Paracetamol tablets exactly as your doctor 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.

Dosage:

Adults, the elderly and children 16 years or older

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Age	500mg tablet	How Often
16 years and over	One -Two	Do not take more than 8 tablets per day (24 hours).

Children:

Age	500mg tablet dose	How Often
6-8 years	Half	Every 4-6 hours when necessary to a maximum of 4 doses in 24 hours
8-10 years	Half	Every 4-6 hours when necessary to a maximum of 4 doses in 24 hours
10-12 years	One	Every 4-6 hours when necessary to a maximum of 4 doses in 24 hours
12-15 years	One-One & half	Every 4-6 hours when necessary to a maximum of 4 doses in 24 hours

Paracetamol Tablets should not be given to children under 6 years of age.**If you take more Paracetamol than you should**

- Talk to your doctor even if you feel well because of the risk of delayed, serious liver damage
- Always take any tablets left over with you, also the box and leaflet as this will allow easier identification of the tablets

If you forget to take Paracetamol Tablets:

If you forget to take a dose, 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, Paracetamol can cause side effects, although not everybody gets them,

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

Severe allergic reactions include:

- difficulty in breathing
- skin rash and itching
- swelling of the face and throat
- runny nose

Rare cases of serious skin reactions have been reported with symptoms like skin reddening, blisters or rash.

Frequency not known: Metabolic acidosis -A serious condition that can make blood more acidic, in patients with severe illness using paracetamol (see section 2)

Other possible side effects

If any of the following side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist:

- Occasionally the blood does not clot well, which may result in easy bruising or bleeding.
- Rarely, a severe reduction in the number

of white blood cells, which makes infections more likely.

- Nausea, sudden weight loss, loss of appetite, abdominal pain and swelling, dark colored urine or stools and yellowing of skin and eyes.

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 Website: www.mhra.gov.uk/yellowcard or search for MHRA yellow card in 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 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 waste water 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 FURTHER 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 a breakline on one side and plain on the other.

The tablet can be divided into equal doses.

Paracetamol Tablets are available in blister packs of 100 tablets.

Marketing Authorisation Holder Flamingo Pharma (UK) Ltd.

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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.

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