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Header's font size : 12 pt.

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Paracetamol 500mg Tablets (FPL) *(GSL)*

Leaflet Size : 285 x 150 mm

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150 mm

285 mm

Pharmacode Reading Direction

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PHARMA CODE

Package leaflet: Information for the patient

Paracetamol 500 mg 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.

WHAT IS IN THIS LEAFLET

1. **What Paracetamol Tablets are and what they are 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 other information**

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

These tablets contain the active ingredient, paracetamol.
Paracetamol is an analgesic and an antipyretic which means it relieves pain and lowers temperature.

Paracetamol Tablets are used for the relief of mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pains, rheumatic aches and pains. Also for the relief of symptoms of influenza, feverishness and feverish colds.

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

Some people must not take these tablets. Do not take Paracetamol Tablets:
- If you are allergic to paracetamol or to any other of the other ingredients of this medicine (listed in section 6).

Do not take anything else containing paracetamol while taking this medicine.

Warnings and precautions
Talk to your doctor or pharmacist before taking Paracetamol Tablets
- If you suffer from any liver or kidney problems
- If you suffer from alcoholic liver disease
- If you suffer from mild arthritis and need to take painkillers every day
- If you are pregnant or breastfeeding

Other medicines and Paracetamol Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This means medicines you have bought yourself as well as those you have on prescription from doctor.

Paracetamol Tablets and other medicines you may be taking may affect how each other work.
Make sure your doctor knows if you are taking/using any of the following:
- Anticoagulants to thin the blood (e.g. warfarin)
- Colestyramine (used to lower the amount of fats in your blood). **Should not be taken at least one hour before and after taking paracetamol**
- Metoclopramide or domperidone (used to nausea and vomiting)
- Chloramphenicol (used to treat conjunctivitis)
- Imatinib (used to treat leukaemia and some stomach tumours).

Pregnancy and breast-feeding
If necessary, Paracetamol 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.

Other special warnings
If you are suffering from a headache and it becomes persistent, consult your doctor.

The tablets contain sodium metabisulphite (E223) which may rarely cause severe hypersensitivity reactions and bronchospasm (breathing difficulties).

Driving and using machines
Paracetamol Tablets should not affect your ability to drive or operate machinery.

3. HOW TO TAKE PARACETAMOL TABLETS

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure. The tablets should be swallowed with a drink of water.

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 for every 4-6 hours when necessary to a maximum of 4 doses in 24 hours.

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.

Dosage should not be continued for more than 3 days without consulting a doctor.

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

If you take more Paracetamol Tablets 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.

If you forget to take Paracetamol Tablets
If you miss a dose don't worry. Do not take a double dose to make up for the forgotten dose, just carry on with the normal routine.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects can be serious. Stop taking the tablets and tell your doctor straight away if you notice the following effects:
- Swelling of the face, lips or throat, difficulty in breathing or dizziness. These may be signs of a serious allergic reaction
- Allergic skin reactions including rash, blistering of the skin, mouth, eyes and genitals
- Breathing problems or wheezing. These effects are more likely if you have asthma and have experienced them before when taking aspirin or other medicines called NSAIDs e.g. ibuprofen
- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin
- Very rare cases of serious skin reactions have been reported.
- Changes in blood which may lead to bruising or bleeding gums. If you have an increase in number of nose bleeds or notice that you bruise more easily or have more infections talk to your doctor

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.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PARACETAMOL 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 carton. The expiry date refers to the last day of that month.

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 Tablets contains
Each tablet contains 500mg of the active ingredient, paracetamol. The other ingredients are progelatnised maize starch, sodium metabisulphite (E223) and magnesium stearate.

What Paracetamol Tablets looks like and contents of the pack.
The tablets are white and capsule shaped with a break line on one side. The tablets are available in blister packs as below:
Blister packs: 8, 12, 16 tablets.
Not all the pack sizes may be available.

Marketing Authorisation Holder:
Flamingo Pharma (UK) Ltd,
1st Floor, Kirkland House,
11-15 Peterborough Road, Harrow,
Middlesex, HA1 2AX,
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Manufacturer:
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If you would like this leaflet in a different format, please contact the licence holder at the above address.

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