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Paracetamol 500mg Capsules (GSL)

Leaflet Size : 295 x 150 mm

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150 mm

295 mm

Pharmacode Reading Direction
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Package leaflet: Information for the user
Paracetamol 500 mg Capsules, Hard
Paracetamol

The name of this medicine is Paracetamol 500mg Capsules, Hard, but will be referred to as Paracetamol Capsules throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This medicine is available without prescription, but you still need to take Paracetamol 500 mg Capsules, Hard carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 Capsules are and what they are used for
2. What you need to know before you take Paracetamol Capsules
3. How to take Paracetamol Capsules
4. Possible side effects
5. How to store Paracetamol Capsules
6. Contents of the pack and other information

1. What Paracetamol Capsules are and what they are used for

Paracetamol 500mg capsules belongs to the group of analgesics and antipyretics and are used for the relief of headache, tension headache, migraine, backache, rheumatic and muscle pain, toothache and period pain. They also relieve sore throat and the fever, aches and pains of colds and flu and are recommended for the relief of pain due to mild arthritis.

The active ingredient is paracetamol which is a painkiller and also reduces your temperature when you have a fever.

2. What you need to know before you take Paracetamol Capsules

Do not take Paracetamol Capsules:

- If you have ever had an allergic reaction to paracetamol or to any of the other ingredients (listed in section 6).
- If you are taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.

Warnings and precautions

Talk to your doctor or pharmacist before taking Paracetamol Capsules if you-

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

Children
This medicine is not recommended in children.

Other medicines and Paracetamol Capsules
Talk to your doctor or pharmacist before taking these capsules if you are taking any prescribed medicines; particularly **metoclopramide** or **domperidone** (for nausea [feeling sick] or vomiting [being sick]) or **colestyramine** (to lower blood cholesterol). If you take **blood thinning drugs (anticoagulants** 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 Capsules at the same time as anticoagulants.

- 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.

Pregnancy and breast-feeding
Talk to your health care professional before taking Paracetamol Capsules if you are **pregnant**. You can take this product whilst **breast feeding**.

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

Driving and using machines
Paracetamol has no influence on the ability to drive and use machines.

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

3. How to take Paracetamol Capsules

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

For oral administration only. The capsules should be swallowed with a drink of water.

Adults, including the elderly:
Swallow 1-2 capsules every 4 to 6 hours as needed.
Do not take more than 8 capsules in 24 hours.

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Dosage instruction:
Do not take more frequently than every 4 hours.
Do not take more than the recommended dose.

If you take more Paracetamol Capsules 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 your symptoms continue or your headache becomes persistent, **see your doctor**.

If you forget to take Paracetamol Capsules
If you forget to take your capsules(s), take the next dose as normal. 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.

A small number of people have had side effects. Very rare cases of serious skin reactions have been reported.

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

- **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.

5. How to store Paracetamol Capsules

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

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 Capsules contains
Each capsule contains 500mg of the active ingredient, paracetamol. The other ingredients are sodium starch glycolate (Type-A), pregelatinised starch, colloidal anhydrous silica and magnesium stearate. The capsule shells are made of gelatin, water, titanium dioxide (E171) and ferric oxide red (E172).

What Paracetamol Capsules looks like and contents of the pack.
The capsules are hard gelatin capsule, with red cap and white base containing a white powder.
The capsules are available in blister packs as below:
Paracetamol Capsules are available in blister packs of 4, 6, 8, 12 or 16 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Fleming Pharma (UK) Ltd,
1st Floor, Kirkland House,
11-15 Peterborough Road,
Harrow, Middlesex,
HA1 2AX, United Kingdom

Manufacturer:
Fleming Pharma (UK) Ltd,
The Bloc,
38 Springfield Way,
Anlaby, Hull,
HU10 6RJ, United Kingdom.

If you would like this leaflet in different format information or want to report any side effect please contact marketing authorization holder listed above.

The leaflet was last revised in **03/2024**.

Product licence number
PL 43461/0087

PHARMA CODE

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GSL

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| Colour Scheme : Black | | | | Ref. Artwork : MPLLPAR0500CPCOMFPLXXX323V01 | |
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| Artwork | Pkg. Development | Marketing | Regulatory | CQA | MAH |
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