



Patient Information Leaflet

1. Name of the Product

Paracetamol Tablets BP 500 mg

2. Description of the Product

White coloured, Beveled edge, uncoated tablets having breakline on one side with “P” and “500” embossed and other side plain.

3. What is in the medicine?

Paracetamol Tablets BP 500 mg contains Paracetamol.

4. Strength of the medicine

Each uncoated tablet contains

Paracetamol BP 500 mg

Excipients Q.S.

5. What is this medicine used for?

Paracetamol tablets belongs to a group of medicines called Analgesics and Antipyretics. It works by relieving pain and reducing high temperature and fever.

Paracetamol tablets are used for the relief of mild to moderate pain including headache, migraine, tension headaches, neuralgia (severe pain in nerves), backache, toothache, sore throat, period pain, symptomatic relief of sprains, strains, rheumatic pain, sciatica (low back pain and leg pain), lumbago (low back pain), fibrositis (muscle and connective tissue pain), muscular aches and pains, joint swelling and stiffness, influenza , feverishness and feverish colds. It may also be used for symptomatic relief of pain due to non-serious arthritis.

6. How much and how often should you use this medicine?

Dosage

Adults, Elderly and Children over 16 years:

Take 1-2 tablets up to four times a day as required. Do not take more than 8 tablets per day (24 hours)



Children 10 – 15 years:

1 tablet every 4 hours as required, to a maximum of 4 tablets in 24 hours.

Leave at least 4 hours between doses.

Do not take with any other paracetamol-containing products.

Do not give to children under 10 years of age.

Do not exceed the stated dose.

If symptoms persist for more than 3 days or get worse consult your doctor or pharmacist.

7. When should you not take this medicine?

Do not take Paracetamol tablets:

- If you are allergic to paracetamol or any of the other ingredients of Paracetamol tablets (see section 6).
- If you are taking any other products that contain Paracetamol.
- If you are under 10 years of age.

Take special care with Paracetamol Tablets

Before taking Paracetamol Tablets, Tell your doctor if:

- you are suffering from liver or kidney disease, including non-cirrhotic alcoholic liver disease.

Taking other medicines

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

In particular, tell your doctor if you are taking any of the following medicines:

- Anticoagulants to thin your blood e.g. warfarin
- Some antibiotics e.g. chloramphenicol
- Medicines to control nausea and vomiting e.g. metoclopramide, domperidone
- Medicines to control high lipid levels e.g. colestyramine
- 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.



8. Undesirable 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

Other possible side effects

- 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.

Very rare cases of serious skin reactions have been reported

10. What should you do if you miss a dose?

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose and just carry on as before. Do not take a double dose to make up for a forgotten dose.

11. How should you keep this medicine?

Keep out of the sight and reach of children.

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

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.



12. Signs and Symptoms of Overdosage

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

If you or someone else swallows several of these tablets all together, or you think a child has swallowed any of these tablets, contact your doctor or pharmacist or hospital emergency department immediately.

Always take any tablets left over with you, also the box and leaflet as this will allow easier identification of the tablets.

13. What to do when you have taken more than the recommended dosage

If you have accidentally taken too many tablets, talk to your doctor straight away, or go to your nearest emergency unit. You may require medical attention. Remember to take your medicine with you, and show it to your doctor or the staff of the emergency unit. If you have run out of tablets, take the empty packaging along with you.

14. Name/Logo of Manufacturer/Importer/Marketing Authorisation Holder

Aura Life Care Pvt Ltd

Sun Enterprises LTD

BP 1952

Kigali, Rwanda

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15. Care that should be taken while taking this medicine

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.

16. Date of Revision of PIL
