

PRODUCT INFORMATION LEAFLET

1. Product Name

Generic Name: Paracetamol Fast Release Tablets

Brand Name: Crocin[®] Advance

2. Qualitative & Quantitative Composition

Each uncoated tablet contains Paracetamol I.P. 500 mg

3. Dosage Form

Oral Tablets

4. Therapeutic indications

Analgesic and Antipyretic

5. Posology and method of administration

1 to 2 tablets every 4 to 6 hours.

Adults and children over 12 years

Maximum dose in 24 hours: 8 tablets i.e. 4000 mg in equally divided doses.

Do not exceed the stated dose.

Do not take more frequently than every 4 hours.

Do not take with any other product containing paracetamol.

Not recommended in children under 12 years.

Do not take more than 3 days without medical advice.

6. Contra-indications

Do not use if you are allergic to paracetamol or any of the other ingredients in the product.

7. Warnings and Precautions

- Check with your doctor before use if you have liver or kidney problems.
- Please see your doctor if your symptoms do not improve.
- Keep out of sight and reach of children.
- May cause Steven Johnson syndrome, very rarely

8. Interaction with other medicaments and other forms of interaction

Before taking this medicine, make sure you consult your doctor if you are taking warfarin or similar medicines used to thin the blood.

9. Pregnancy and lactation

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

10. Effects on ability to drive and use machines, if contra-indicated

None

11. Undesirable effects/side effects

Stop taking this medicine and tell your doctor immediately if:

- you experience allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- you experience a skin rash or peeling, or mouth ulcers.
- you have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatory drugs, and experience a similar reaction with this product.
- you experience unexplained bruising or bleeding.

These reactions are rare.

12. Overdose

If you take more of the medicine then you should seek medical advice immediately because of the risk of liver failure.

13. List of excipients

1. Pregelatinised Maize starch B.P (Lycatab PGS)
2. Calcium Carbonate
3. Povidone I.P
4. Crospovidone I.P (Kollidon CL)
5. Nipasept Sodium (Combination of Sodium Methyl paraben, Sodium Ethyl Paraben and Sodium Propyl paraben)
6. Alginic acid
7. Colloidal silicone dioxide I.P (Aerosil 200)
8. Magnesium stearate I.P
9. Purified Water I.P.

14. Incompatibilities

Not applicable

15. Shelf life

24 months

16. Special precautions for storage

- Store at a temperature not exceeding 40°C.
- Protect from direct sunlight and moisture.

17. Nature and specification of the container

PVC-Aluminium foil blister pack of 15 tablets