PRODUCT INFORMATION LEAFLET

1. Product Name

Brand Name: Crocin Advance
Generic Name: Paracetamol Fast Release Tablets

2. Qualitative & Quantitative Composition

Each uncoated tablet contains:
Paracetamol I.P. 500 mg

3. Dosage Form

Oral Tablets

4. Clinical Particulars

4.1. Indications/Uses

Crocin Advance is used as Analgesic and Antipyretic- In the treatment of fever and treatment of mild-to-moderate pain e.g. Headache, Musculoskeletal pain, Toothache etc.

4.2. Posology and method of administration

Dosage for Adults and children over 12 years: 1 to 2 tablets every 4 to 6 hours as required, not more than 8 tablets in any 24 hours period. Minimum dosing interval- 4 hours. Maximum daily dose: 4000 mg. Do not take this medicine more than 3 days without medical advice.

Do not exceed the stated dose.

Use the smallest dose that you need to treat your symptoms and use the medicine for the shortest period of time necessary.

Crocin Advance is not recommended in children under 12 years of age.

4.3. Contra-indications

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

4.4. Warnings and Precautions

Crocin Advance contains Paracetamol. Do not take more than the recommended dose as it may cause serious harm to your liver. Do not use this medicine 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.
Always read and follow the label

Check with your doctor before use if you:

- have liver or kidney problems.
- have a severe infection, are severely malnourished, severely underweight or are a chronic heavy alcohol user, or have sepsis or depleted glutathione levels 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. Please see your doctor if your symptoms do not improve.
  Keep out of sight and reach of children

Each tablet contains 173 mg of sodium (346 mg sodium per 2 tablet dose). To be taken into consideration by patients on a controlled sodium diet.

4.5. 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.

4.6. Pregnancy and lactation

Pregnancy: As with the use of any medicine during pregnancy, pregnant women should seek medical advice before taking paracetamol. The lowest effective dose and shortest duration of treatment should be considered.

Lactation: Paracetamol is excreted in breast milk but not in a clinically significant amount at recommended dosages. Available published data do not contraindicate breastfeeding. Hence, can be taken during breastfeeding.

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

None

4.8. 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.

4.9. Overdose

In case of over dosage, seek medical advice from a doctor immediately even if you do not have any symptoms because of the risk of liver failure. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.
High doses of sodium bicarbonate may be expected to induce gastrointestinal symptoms including belching and nausea. In addition, high doses of sodium bicarbonate may cause hypernatraemia; electrolytes should be monitored and patients managed accordingly

In case of over dosage, you may also contact the **National Poisons Information Centre of India. Details of the same are as below:**
Department of Pharmacology
All India Institute of Medical Sciences
New Delhi-110029
Toll Free No. - 1800 116 117
Tel No.- 26589391, 26593677
E-mail: npicaiims2010@gmail.com

Administration of N-acetylcysteine or methionine may be required.

5. Pharmacological Properties

5.1. Pharmacodynamic Properties &/ or mechanism of action

Mechanism of Action
Paracetamol is an analgesic and antipyretic. Its mechanism of action is believed to include inhibition of prostaglandin synthesis, primarily within the central nervous system.

Paracetamol tablets with Optizorb contain a disintegrant system which optimizes tablet dissolution compared to standard paracetamol tablets.

6. Pharmaceutical Particulars

6.1. List of Excipients

Pregelatinised Maize starch
Calcium Carbonate
Povidone K-25
Crospovidone
Alginic acid
Colloidal silicone dioxide
Magnesium stearate
Purified Water

6.2. Incompatibilities
Not applicable

6.3. Shelf life
24 months

6.4. Special storage conditions
Keep out of sight and reach of children.
Store at ambient room temperature protected from light and moisture.

6.5. Nature and specification of the container
15 and 20 tablets blister (Aluminium/PVC).

6.6. Instructions for Use and Handling
No special instructions for use and handling.

6.7. Manufacturing License Holder
Refer pack for details on manufacturing license holder

6.8. Marketed By
GlaxoSmithKline Asia Private Limited,
Patiala Road, Nabha- 147201, Punjab, India

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