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.

4.2. Posology and method of administration

Dosage for Adults and children over 12 years: 1 to 2 tablets every 4 to 6 hours. Do not take more frequently than every 4 hours and not more than 8 tablets per 24 hours. 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. Do not take this medicine more than 3 days without medical advice.

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 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.

Crocin Advance contains Nipasept Sodium (Combination of Sodium Methyl paraben, Sodium Ethyl Paraben and Sodium Propyl paraben). As parabens are derivative of benzoic acid, this may increase jaundice (yellowing of the skin and eyes) in babies.

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.

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

5. Pharmacological Properties

5.1. Pharmacodynamic Properties & mechanism of action

ATC code: N02B E01
Pharmacotherapeutic group: Anilides

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.

Pharmacodynamic Effects

The lack of peripheral prostaglandin inhibition confers important pharmacological properties such as the maintenance of the protective prostaglandins within the gastrointestinal tract. Paracetamol is, therefore, particularly suitable for patients with a history of disease or patients taking concomitant medication in whom peripheral prostaglandin inhibition would be undesirable (such as, for example, those with a history of gastrointestinal bleeding or the elderly).
Paracetamol tablets with Optizorb at the 500 mg dose also demonstrated superior efficacy compared to placebo.

5.2. Pharmacokinetics

Absorption: Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract.
Distribution: Binding to the plasma proteins is minimal at therapeutic concentrations.

Metabolism: Paracetamol is metabolised in the liver and excreted in the urine mainly as glucuronide and sulphate conjugates.

Elimination: Less than 5% is excreted as unmodified paracetamol. The mean plasma half life is about 2.3 hours.

Paracetamol tablets with Optizorb contain a distintegrant system which optimizes tablet dissolution compared to standard immediate release paracetamol tablets. Human scintigraphy data demonstrate that paracetamol tablets with Optizorb generally start to disintegrate by 5 minutes' post dose.

6. Pharmaceutical Particulars

6.1. List of Excipients

Pregelatinised Maize starch
Calcium Carbonate
Povidone K-25
Crospovidone
Nipasept Sodium (Combination of Sodium Methyl paraben, Sodium Ethyl Paraben and Sodium Propyl paraben)
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 tablets blister (Aluminium/PVC).

6.6. Instructions for Use and Handling

No special instructions for use and handling.

6.7. Manufacturing License Holder

Remidex Pharma Pvt Ltd.
B- 249/250, Peenya II Stage, Bangaluru 560058, India

6.8. Marketed By

GlaxoSmithKline Asia Private Limited,
Patiala Road, Nabha- 147201, Punjab, India

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