

## 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 as this may increase the risk of metabolic acidosis.

**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 &/ 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

ENCORE HEALTHCARE PVT. LTD.  
Plot No -D-5, M.I.D.C., Industrial area, Paithan, Aurangabad - 431148

**6.8. Marketed By**

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

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