

**PRODUCT INFORMATION LEAFLET**

**1. Product Name**

**Brand Name:** Crocin Pain Relief

**Generic Name:** Acetaminophen and Caffeine Tablets USP

**2. Qualitative & Quantitative Composition**

Each uncoated tablet contains:

Paracetamol I.P. 650 mg

Caffeine Anhydrous I.P. 50 mg

**3. Dosage Form**

Oral Uncoated Tablets

**4. Clinical Particulars**

**4.1. Indications/Uses**

Crocin Pain Relief contains paracetamol, which is an analgesic and antipyretic, and caffeine, an adjuvant to the analgesic effect of paracetamol.

Crocin Pain Relief is used for the treatment of mild to moderate pain including, headache, migraine, toothache, period pain, Pain of osteoarthritis and musculoskeletal pains.

**4.2. Posology and method of administration**

**Dosage for Adults and children over 12 years:** 1 tablet every 4 to 6 hours.

Do not take more frequently than every 4 hours and not more than 6 tablets per 24 hours. Do not exceed the stated dose.

Always use the lowest effective dose to relieve your symptoms.

Crocin Pain Relief 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**

Crocin Pain Relief is contraindicated in patients with a previous history of hypersensitivity to paracetamol, caffeine or any of the other ingredients in the product.

**4.4. Warnings and Precautions**

Crocin Pain Relief contains Paracetamol. Taking too much paracetamol can cause serious harm to your liver. Do not take 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*

## CROCIN PAIN RELIEF

### **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.

You may also need to avoid using the product altogether or limit the amount of paracetamol that you take.

This medicine contains caffeine. Avoid drinking too many caffeine containing drinks (eg. tea, coffee and caffeine containing canned drinks) when taking this medicine. High caffeine intake can result in difficulty sleeping, shaking and an uncomfortable feeling in the chest caused by fluttering heartbeat.

Please see your doctor if your symptoms do not improve.

### **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:* Not recommended for use during pregnancy.

*Lactation:* Use during breast-feeding should be avoided.

### **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**

## CROCIN PAIN RELIEF

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: Paracetamol: Anilides

Caffeine: Methylxanthine

Paracetamol is an antipyretic and analgesic. Its mechanism of action is believed to include inhibition of prostaglandin synthesis, primarily within the central nervous system. 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, where peripheral prostaglandin inhibition would be undesirable (for example, those with a history of gastrointestinal bleeding or in the elderly).

Caffeine acts as an analgesic adjuvant which enhances the efficacy of paracetamol. Clinical data have demonstrated that paracetamol-caffeine provides superior pain relief compared to standard paracetamol tablets ( $p \leq 0.05$ ). Caffeine is a methylxanthine and a non-selective adenosine receptor antagonist.

### 5.2. Pharmacokinetics

Paracetamol is rapidly absorbed from the gastrointestinal tract and is distributed into most body tissues. Binding to plasma proteins is minimal at therapeutic concentrations. Paracetamol is metabolised in the liver and excreted in the urine mainly as glucuronide and sulphate metabolites - less than 5% is excreted as unmodified paracetamol. The mean plasma half-life is about 2.3 hours.

Caffeine is rapidly absorbed from the gastrointestinal tract and is widely distributed throughout the body. Caffeine is almost completely metabolized in the liver by oxidation and demethylation to various xanthine derivatives, which are excreted in the urine. The mean plasma half-life after oral administration is about 4.9 hours.

## **CROCIN PAIN RELIEF**

### **6. Pharmaceutical Particulars**

#### **6.1. List of Excipients**

Pregelatinised Maize starch  
Maize Starch  
Povidone K-25  
Croscarmellose Sodium  
Potassium Sorbate  
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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