

PRODUCT INFORMATION LEAFLET

1. Product Name

Brand Name: Crocin Cold & Flu Max

Generic Name: Paracetamol, Caffeine and Phenylephrine Hydrochloride Tablets

2. Qualitative & Quantitative Composition

Each uncoated tablet contains:

Paracetamol I.P. 500 mg

Caffeine (as anhydrous) I.P. 32 mg

Phenylephrine Hydrochloride I.P. 10 mg

3. Dosage Form

Oral Uncoated Tablets

4. Clinical Particulars

4.1. Indications/Uses

Crocin Cold & Flu Max is Decongestant, Analgesic and Antipyretic Tablet. It is used for the relief of sinus pain and the cold and flu symptoms (nasal congestion/stuffy nose, headache, body ache, sore throat pain).

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 4 tablets per 24 hours. Do not exceed the stated dose.

Always use the lowest effective dose to relieve your symptoms.

Crocin Cold and flu Max is not recommended in children under 12 years of age. Do not use for longer than 7 days without medical advice.

4.3. Contra-indications

Do not use Crocin Cold & Flu Max if:

- You are allergic to paracetamol, caffeine, phenylephrine or any of the other ingredients in the product.
- You are taking, or have taken in the past two weeks, drugs called monoamine oxidase inhibitors (MAOIs), usually used to treat depression.
- You are pregnant.

4.4. Warnings and Precautions

Crocin Cold & Flu Max contains Paracetamol. Taking too much paracetamol can cause serious harm to your liver. Do not take with any other medicines for the relief of colds and flu, congestion or blocked nose.

CROCIN COLD & FLU MAX

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.

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

- have high blood pressure, heart disease, blood vessel disease such as Raynaud's phenomenon (which may appear as pain in the fingers or toes in response to cold or stress), diabetes, an overactive thyroid, glaucoma (excessive pressure inside your eyes), pheochromocytoma (a tumour near the kidney), or prostate problems.
- are breast-feeding. Use during breast-feeding should be avoided.

This medicine contains caffeine. Avoid drinking too many caffeine containing drinks (eg. tea, coffee and caffeine containing canned drinks) when taking this medicine.

Please see your doctor if your symptoms persist.

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.
- are taking appetite suppressants or stimulants.
- are taking medicines to control your blood pressure, such as beta-blockers.
- are taking medicines to treat depression, such as tricyclic antidepressants (e.g. amitriptyline).
- are taking medicines for heart disease (e.g. digoxin).

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

This medicine may cause dizziness. If affected do not drive or operate machinery.

4.8. Undesirable effects/side effects

When using this medicine you may experience: Headache, dizziness, nervousness, difficulty sleeping, increased blood pressure, nausea and vomiting.

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.
- you experience loss of vision, which may be due to abnormally high blood pressure in the eye. This is very rare but is more likely to occur in those with glaucoma.
- you experience an unusually fast pulse rate, or a sensation of an unusually fast or irregular heartbeat.
- you experience difficulty in passing water. This is more likely to occur in men with an enlarged prostate gland.

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 E51

Pharmacotherapeutic group: Other analgesics and antipyretics and Other Cold Combination Products.

Paracetamol

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, where peripheral prostaglandin inhibition would be undesirable (for example, those with a history of gastrointestinal bleeding or in the elderly).

Caffeine

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 ($p \leq 0.05$).

Phenylephrine hydrochloride

Phenylephrine hydrochloride is a sympathomimetic agent with mainly direct effects of adrenergic receptors (predominantly alpha-adrenergic activity) producing nasal decongestion. It is used as a nasal decongestant for the symptomatic relief of nasal congestion associated with colds and influenza.

5.2. Pharmacokinetics

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract and distributed into most body tissues. Binding to plasma proteins is minimal at therapeutic concentrations.

It 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 widely distributed.

It is almost completely metabolised in the liver by oxidation and demethylation to various xanthine derivatives, which are excreted in the urine. The mean plasma half life is about 4.9 hours.

Phenylephrine is irregularly absorbed from the gastrointestinal tract.

It undergoes first-pass metabolism by monoamine oxidases in the gut and liver; orally administered phenylephrine thus has reduced bioavailability. It is excreted in the urine almost entirely as the sulphate conjugate.

6. Pharmaceutical Particulars

6.1. List of Excipients

Pregelatinised Maize starch
Maize Starch
Povidone K-25
Sodium Lauryl Sulphate
Potassium Sorbate
Microcrystalline Cellulose
Purified Talc
Stearic Acid
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

***Crocin is a trademark owned by or licensed to the GSK Group of companies**