PRODUCT INFORMATION LEAFLET

1. Product Name

Brand Name: Crocin C & F 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

For the relief of sinus pain and the cold and influenza symptoms of:

- nasal and sinus congestion
- minor aches and pains, such a sore throat, headache and muscle ache
- fever

4.2. Posology and method of administration

For Oral administration only.

Dosage for adults and children aged 12 years and over: 1 tablet every 4 to 6 hours as required with minimum dosing interval of 4 hours.
Maximum daily dose: 6 tablets in any 24-hour period (paracetamol 3000 mg, Caffeine 192 mg and Phenylephrine Hydrochloride 60 mg)
Do not exceed the stated dose.

Lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment. Do not use for longer than 7 days without medical advice. If your symptoms do not improve, consult your doctor.

Crocin C & F Max is not recommended for children under 12 years of age.

4.3. Contra-indications

Do not use Crocin C & F Max if:

- You have prior hypersensitivity/ allergies to paracetamol, caffeine, phenylephrine hydrochloride or any of the excipients *(see section 6.1).*

- You are taking, or have taken monoamine oxidase inhibitors (MAOIs) within the last two weeks (see *Interactions*)
  You are pregnant or trying to become pregnant.

4.4. Warnings and Precautions

Do not use this medicine if you are taking any other prescription or non-prescription medicines containing paracetamol or other cold & flu medications.
Do not take more than the recommended dose as it may cause serious harm to your liver.
Always read and follow the label. Keep out of sight and reach of children.

Check with a doctor before use if you have:

- Depleted glutathione levels, such as those who are severely malnourished, underweight, anorexic, have a low body mass index, are chronic heavy users of alcohol or have sepsis (severe infection).
- Hepatic or renal impairment (liver or kidney problems).
- Hypertension (high blood pressure)
- Cardiovascular disease (heart disease)
- Diabetes (too much sugar in your blood)
- Hyperthyroidism (an overactive thyroid gland)
- Angle closure glaucoma ((increased pressure inside your eyes)
- Phaeochromocytoma (a rare tumour of the adrenal glands which sit above the kidneys)
- difficulty urinating due to an enlarged prostate gland.
- Occlusive vascular disease (e.g. Raynaud's phenomenon)

Use with caution in patients taking the following medications (see Interactions):

- Beta-blockers and other antihypertensives.
- Tricyclic antidepressants.
- Other sympathomimetics (such as decongestants, appetite suppressants and amphetamine-like medicines),
- Digoxin and cardiac glycosides.
- Ergot alkaloids (e.g. ergotamine and methysergide).

Excessive intake of caffeine (e.g. coffee, tea and some canned drinks) should be avoided while taking this product.

4.5. Interaction with other medicaments and other forms of interaction

Ingredients of Crocin C & F Max are known to interact with below mentioned drugs/class of drugs, please consult your doctor before taking Crocin C & F Max if you are on any of these medications:

- Monoamine oxidase inhibitors
- Sympathomimetic amines
- Beta-blockers and other antihypertensives (including debrisoquine, guanethidine, reserpine, methyldopa)
- Tricyclic antidepressants (e.g.amitriptyline)
- Digoxin and cardiac glycosides
- Ergot alkaloids (e.g. ergotamine and methysergide)
- Warfarin and other coumarins
- Lithium

4.6. Pregnancy and lactation

Do not take Crocin C & F Max if you are pregnant or trying to become pregnant. Avoid the use of the product during lactation period.

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

Known adverse reactions of the ingredient/s are:

Paracetamol: Thrombocytopaenia, anaphylaxis, cutaneous hypersensitivity reactions including among others, toxic epidermal necrolysis, Stevens Johnson syndrome, angioedema and skin rashes, bronchospasm in patients sensitive to aspirin and other NSAIDs, hepatic dysfunction.

Caffeine: Dizziness, headache, insomnia, restlessness, anxiety and irritability, nervousness, palpitation, gastrointestinal disturbances.

Phenylephrine hydrochloride: Nervousness, headache, dizziness, insomnia, increased blood pressure, nausea, vomiting, hypersensitivity, allergic dermatitis, urticaria, acute angle closure glaucoma, most likely to occur in those with closed angle glaucoma, mydriasis, tachycardia, palpitations, rash, urinary retention, dysuria.

4.9. Overdose

In case of overdose, consult doctor.

Below are the details of India's National Poison Information Centre, in case of overdosage, you may also contact here.

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. Pharmacodynamic Properties &/ or mechanism of action

Pharmacotherapeutic group: Analgesic, Antipyretic & decongestant

Mechanism of Action

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

Caffeine
The analgesic adjuvant effects of caffeine have been proposed to result from several mechanisms: (i) blockade of peripheral pronociceptive actions of adenosine; (ii) activation of central noradrenergic pathways that constitute an endogenous pain suppressing system; and (iii) CNS stimulation with a consequent modulation of the affective component of pain.

Phenylephrine hydrochloride
Phenylephrine hydrochloride is a sympathomimetic agent with mainly direct effects of adrenergic receptors (predominantly alpha-adrenergic activity) producing nasal decongestion.

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

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