

PRODUCT INFORMATION LEAFLET

1. Product Name

Crocine Cold n' Flu[®] tablets

2. Qualitative & Quantitative Composition

Each film coated tablet contains:

Paracetamol I.P. 500 mg, Caffeine I.P. (anhydrous) 32 mg,

Phenylephrine Hydrochloride I.P 10 mg

3. Dosage Form

Oral tablets

4. Therapeutic indications

Decongestant, Analgesic and Antipyretic Tablets

For effective relief from multiple symptoms like nasal congestion/stuffy nose, headache, sinus pain, body ache, sore throat pain and chills.

5. Posology and method of administration

For mild to moderate symptoms – 1 tablet 3 to 4 times a day.

For severe symptoms – 2 tablets 3 to 4 times a day.

Not suitable for children under 12 years of age.

Do not take more than 8 tablets in 24 hours in 24 hours.

Do not use for longer than 7 days without asking your doctor.

Do not exceed the stated dose and do not take more frequently than every 4 hours.

Do not take with any other product containing paracetamol, or with medicines for the relief of colds and flu, congestion or blocked nose.

6. Contra-indications

Do not use 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.

7. Warnings and Precautions

- Check with your doctor before use if:

- you have liver or kidney problems.
- you 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 tumor near the kidney), or prostate problems.
- you are taking medicines to control your blood pressure, such as beta-blockers.
- you are taking appetite suppressants or stimulants.
- you are taking medicines to treat depression, such as tricyclic antidepressants (e.g. amitriptyline).
- you are taking medicines for heart disease (e.g. digoxin).
- you are taking warfarin or similar medicines used to thin the blood.
- you are breast-feeding. Use during breast-feeding should be avoided.
- This medicine contains caffeine. Avoid drinking too many caffeine containing drinks (e.g. tea, coffee and caffeine containing canned drinks) when taking this medicine.
- Please see your doctor if your symptoms persist.
- Keep out of sight and reach of children

8. Interaction with other medicaments and other forms of interaction

Medical advice should be sought before taking paracetamol-caffeine phenylephrine in combination with the following drugs: Monoamine oxidase inhibitors, Sympathomimetic amines, Beta-blockers and other antihypertensives (including debrisoquine, guanethidine, reserpine, methyldopa), Tricyclic antidepressants (eg amitriptyline), Digoxin and cardiac glycosides, Warfarin and other coumarins.

9. Pregnancy and lactation

- This product is not recommended for use in pregnancy due to the phenylephrine and caffeine content. There is a potential increased risk of lower birth weight and spontaneous abortion associated with caffeine consumption during pregnancy.
- This product should not be used while breast-feeding without medical advice
- Caffeine in breast milk may have a stimulating effect on breast-fed infants.
- Phenylephrine may be excreted in breast milk. It should not be used while breast feeding without medical advice.

10. Effects on ability to drive and use machines, if contra-indicated

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

11. 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.

12. Overdose

If you take more of the medicine, then you should seek medical advice immediately because of the risk of liver failure.

13. List of excipients

1. Maize Starch I.P.
2. Pregelatinised Maize Starch BP
3. Povidone IP (K-25)
4. Sodium Lauryl Sulphate IP
5. Potassium Sorbate BP/Ph. Eur
6. Microcrystalline cellulose IP (Avicel PH 101)
7. Purified talc IP
8. Stearic acid I.P.
9. Instacoat Universal IC-U-5712
10. Purified Water IP

14. Incompatibilities

None

15. Shelf life

24 months from the date of manufacturing

16. Special precautions for storage

Store at room temperature

17. Nature and specification of the container

PVC and Aluminium foil Blister pack of 2 × 6' tablets.