

PRODUCT INFORMATION LEAFLET

1. Product Name

Crocin® Pain Relief Tablets (Acetaminophen and Caffeine Tablets USP)

2. Qualitative & Quantitative Composition

Each uncoated tablet contains Paracetamol IP 650 mg, Caffeine Anhydrous IP 50 mg

3. Dosage Form

Oral tablets

4. Therapeutic Indications

Analgesic

For symptomatic relief from mild to moderate pain e.g. headache, migraine, toothache, period pain and musculoskeletal pains.

5. Posology and method of administration

1 tablet, 3 to 4 times in any 24-hour period or as directed by physician

Maximum dose in any 24-hour period: 4 tablets in equally divided doses.

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

Not suitable for children under the age of 12 years.

Do not take with any other product containing paracetamol.

6. Contra-indications

Do not use if you are allergic to paracetamol, caffeine or any of the other ingredients in the product.

7. Warnings and Precautions

- Check with your doctor before use if you have liver or kidney problems.
- This medicine contains caffeine. Avoid drinking too many caffeine containing drinks (e.g. 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.
- Keep out of sight and reach of children.

8. 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.

9. Pregnancy and lactation

- Not recommended for use during pregnancy.
- Use during breast-feeding should be avoided.

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

None

11. 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

12. Overdose

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

13. List of excipients

1. Maize Starch IP
2. Pregelatinised Maize Starch BP
3. Potassium Sorbate Ph Eur.
4. Povidone K 25 (Plasdone K-25) USNF
5. Caffeine Anhydrous (Granular)IP
6. Croscarmellose Sodium USNF (Ac-di-sol)
7. Magnesium Stearate IP
8. Purified Water IP

14. Incompatibilities

None

15. Shelf life

24 months from the date of manufacturing

16. Special precautions for storage

- Store at ambient room temperature, not exceeding 40°C.
- Protect from direct sun light.

17. Nature and specification of the container

Blister pack of Clear PVC and Aluminium foil with 10 tablets