

PRODUCT INFORMATION LEAFLET

1. Product Name

Crocin® Suspension (Paracetamol Oral Suspension IP 120 mg/5ml)

Crocin® Suspension DS (Paracetamol Oral Suspension IP 240 mg/5ml)

2. Qualitative & Quantitative Composition

Crocin® Suspension

Each 5 ml contains Paracetamol IP 120 mg in flavored syrupy base

Color: Carmoisine

Crocin® Suspension DS

Each 5 ml contains Paracetamol IP 240 mg in flavored syrupy base

Color: Carmoisine

3. Dosage Form

Oral Suspension

4. Therapeutic indications

Analgesic and Antipyretic

5. Posology and method of administration

15 mg/kg per dose

Crocin® Suspension

- Age 1-2 years, average weight 10-12 kg, dose 6-8 ml
- Age 2-3 years, average weight 12-14 kg, dose 8-9 ml
- Age 3-4 years, average weight 14-18 kg, dose 9-11 ml
- Age 4-5 years, average weight 18-20 kg, dose 11-13 ml

Crocin® Suspension DS

- Age 5-7 years, average weight 20-25 kg, dose 6-8 ml
- Age 7-9 years, average weight 25-32 kg, dose 8-10 ml
- Age 9-11 years, average weight 32-40 kg, dose 10-13 ml
- Age 11-12 years, average weight 40-45 kg, dose 13-14 ml

In each case, not more than 4 doses in any 24 hour period or as directed by physician. Minimum dosing interval: 4 hours. Do not take more than 60mg/kg presented in divided doses of 15mg/kg throughout the 24 hour period. Always dose by body weight of child. Not to be administered for more than 48 hours without doctor's advice.

6. Contra-indications

- Should not be used along with other paracetamol containing products.
- Do not use if you are allergic to paracetamol or any of the other ingredients in the product.

7. Warnings and Precautions

- Consult your doctor before use if you have liver or kidney problems.
- Please see your doctor if your symptoms do not reduce.
- Keep out of reach and sight 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 applicable

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-inflammatories, 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

Crocin® Suspension

Crocin® Suspension 120 mg/5ml and 240 mg/5ml

1. Sugar S-30 Grade
2. Sorbitol Solution 70 % IP
3. Methyl Paraben IP
4. Propyl Paraben IP
5. Citric acid Monohydrate IP
6. Carbopol 974P USNF
7. Strawberry Flavour 258581
8. Carmoisine
9. Sodium Hydroxide IP
10. Purified Water IP

Crocin® Suspension DS

1. Sugar S-30 Grade
2. Sorbitol Solution 70 % IP
3. Methyl Paraben IP
4. Propyl Paraben IP
5. Citric acid Monohydrate IP
6. Carbopol 974P USNF
7. Masking Flavor 501483T
8. Mixed Fruit Flavor 591956 T8
9. Carmoisine
10. Sodium Hydroxide IP
11. 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, Protected from light & moisture.

17. Nature and specification of the container

60 ml Amber colored bottles with Child resistant caps along with a measuring cup.

18. Instruction for use and Handling

Shake well before use
Use measuring cup for correct dosing