PRODUCT INFORMATION LEAFLET

1. Product Name

Brand Name: Crocin 120
Generic Name: Paracetamol Paediatric Oral Suspension I.P.

2. Qualitative & Quantitative Composition

Each 5 ml contains:
Paracetamol I.P. 120 mg
In flavoured syrup base.
Colour: Carmoisine

3. Dosage Form

Oral Suspension

4. Clinical Particulars

4.1. Indications/Uses

Analgesic and Antipyretic.

4.2. Posology and method of administration

For Oral administration only.

Dosage: 10-15 mg/kg per dose

Average Weight (Kg)	Dose* (ml)
10-12	6-7
12-14	7-8
14-18	8-11
18-20	11-12

*****Calculated based on 15 mg/kg body weight.

Maximum daily dosage is 60 mg/kg to be administered in divided doses of 10-15 mg/kg throughout the 24-hour period.
Do not take more frequently than every 4 hours. Always dose by body weight of child. Do not take this medicine for more than 3 days without consulting doctor. Do not exceed the stated dose.

For Children under 1 month: Not Recommended.
For children under 3 months: If fever persists for more than 24 hours (4 doses) seek medical advice. This is to ensure that fever that may be due to a serious infection is quickly diagnosed.
Use measuring cup available with the pack to measure the accurate dose.

Use the smallest dose that you need to treat your symptoms and use the medicine for the shortest period of time necessary.

4.3. Contra-indications

Do not use Crocin 120 if child is allergic to paracetamol or any of the other ingredients in the product.

4.4. Warnings and Precautions

Crocin 120 contains Paracetamol. Do not take more than the recommended dose as it may cause serious harm to your liver. 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

In case of any of the below situations, you may need to avoid using this product altogether or limit the amount of paracetamol that you take.

Check with your doctor before use if the child:

- has liver or kidney problems.
- has depleted glutathione levels, such as those who have a severe infection, are severely malnourished, severely underweight 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. Please see your doctor if your symptoms do not improve.
Keep out of sight and reach of children.

Crocin 120 contains Methyl paraben and Propyl paraben paraben which may cause allergic reactions (possibly delayed). As parabens are derivative of benzoic acid, this may increase jaundice (yellowing of the skin and eyes) in babies.

Each 5 ml of suspension contains 1250 mg of Sorbitol solution 70%. Patients with rare hereditary problem of fructose intolerance should not take this medicine. This medicine may have a mild laxative effect and cause gastrointestinal discomfort.

4.5. Interaction with other medicaments and other forms of interaction

Before taking this medicine, make sure you consult your doctor if child is taking warfarin or similar medicines used to thin the blood.

4.6. Pregnancy and lactation

Pregnancy: As with the use of any medicine during pregnancy, pregnant women should seek medical advice before taking paracetamol. The lowest effective dose and shortest duration of treatment should be considered.

Lactation: Paracetamol is excreted in breast milk but not in a clinically significant amount at recommended dosages. Available published data do not contraindicate breastfeeding. Hence, can be taken during breastfeeding.

4.7. Effects on ability to drive and use machines, if contra-indicated
None

4.8. 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.

4.9. Overdose

In case of overdosage, 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 overdosage, 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
E-mail: npicaiims2010@gmail.com

5. Pharmacological Properties

5.1. Pharmacodynamic Properties & mechanism of action
ATC code: N02B E01
Pharmacotherapeutic group: Anilides

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

5.2. Pharmacokinetics

Absorption: Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract.
Distribution: Binding to the plasma proteins is minimal at therapeutic concentrations.

Metabolism: Paracetamol is metabolised in the liver and excreted in the urine mainly as glucuronide and sulphate conjugates.
Elimination: Less than 5% is excreted as unmodified paracetamol.

6. Pharmaceutical Particulars

6.1. List of Excipients

Sucrose
Xanthan Gum
Methyl Paraben
Propyl Paraben
Sodium Citrate
Citric Acid Monohydrate
Sorbitol Solution 70% NC
Microcrystalline cellulose
Sodium carboxy methyl cellulose
Carmoisine
Strawberry Flavour
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

60 ml and 100ml Amber colored PET bottles with ROPP cap along with a measuring cup.

6.6. Instructions for Use and Handling

Shake Well Before Use. Use measuring cup for correct dosing.

6.7. Manufacturing License Holder

Refer pack for details on manufacturing license holder.

6.8. Marketed By

GlaxoSmithKline Asia Private Limited,
Patiala Road, Nabha- 147201, Punjab, India

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