PRODUCT INFORMATION LEAFLET

1. Product Name

Brand Name: Crocin Liquid (15 ml pack with dropper – Baby Drops & 60 ml pack with measuring cup – MAX suspension)
Generic Name: Paracetamol Paediatric Oral Suspension I.P.

2. Qualitative & Quantitative Composition

Each ml contains:
Paracetamol I.P. 100 mg
In flavoured syrup base.
Permitted Colour: Quinoline Yellow WS.

3. Dosage Form

Oral Suspension

4. Clinical Particulars

4.1. Indications/Uses

Analgesic and Antipyretic.

4.2. Posology and method of administration

For Only administration only.

Dosage: 10-15 mg/kg per dose

15 ml pack with Dropper (Baby Drops)

Average Weight (Kg)	Dose* (ml)
3.8-5.5	0.5-0.8
5.5-8.3	0.8-1.2
8.3-10	1.2-1.5

*****Calculated based on 15 mg/kg body weight.
Use dropper available with the pack to measure the accurate dose.

60 ml pack with measuring cup (MAX Suspension)

Dosage under 12 years *	
Weight (Kgs)	**Single Dose* (ml)**
12-15	1.8 – 2.3
15-20	2.3 - 3
20-25	3-3.75
25-32	3.75 – 4.8
32-40	4.8 - 6

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

12 years and above: 5-10 ml/single dose, 3-4 times a day. Dosages are for reference purposes only. Consult doctor for advice. Preferred lower dose while rounding off during dose calculation. Do not exceed 4000 mg/24 hours.

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

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.

4.3. Contra-indications

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

4.4. Warnings and Precautions

Crocin Liquid 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.

Crocin Liquid contains Methyl paraben and Propyl 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.

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 over dosage, 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 over dosage, 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
Liquid Glucose
Xanthan Gum
Glycerin
MonoAmmonium Glycyrrhizinate
Methyl Paraben
Propyl Paraben
Sodium Metabisulphite
Sodium Chloride
Sodium Citrate
Citric Acid Monohydrate
Quinoline yellow WS
Peppermint Flavour C
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 ml Amber colored bottles with ROPP cap along with a measuring dropper.
60 ml Amber colored PET bottle with Child resistant cap along with a measuring cup.

6.6. Instructions for Use and Handling
Shake Well Before Use.

6.7. Manufacturing License Holder
Refer pack for the details of manufacturer.

6.8. Marketed By
GlaxoSmithKline Asia Private Limited,
Patiala Road, Nabha- 147201, Punjab, India

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