

PARAMOL®
120 mg / 5 mL syrup

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about PARAMOL

Each 5 mL of PARAMOL syrup contains 120 mg paracetamol. Paracetamol (also named acetaminophen) is a clinically proven safe and effective analgesic and antipyretic.

Paracetamol produces analgesia by elevation of the pain threshold and reduces fever through action on the hypothalamic heat-regulating center.

PARAMOL reduces fever and relieves aches and pains due to the common cold, flu, headaches, sore throat, vaccinations, toothaches, teething or childhood infections.

PARAMOL can be administered safely for infants and children.

The way to take PARAMOL

PARAMOL must be administered as directed. Dosage is generally individualized according to the child's weight. Do not exceed the maximum recommended dosage. The usual recommended daily dosage is 60 mg/kg/day divided in 4 to 6 doses; 15 mg/kg every 6 hours or 10 mg/kg every 4 hours.

Age	Dose
2 to 3 months	2,5 mL per dose, maximum 10 mL per day
4 to 11 months	2.5 mL to 5 mL per dose, maximum 15 mL per day
12 to 23 months	5 mL per dose, maximum 25 mL per day
2 to 3 years	5 mL to 7.5 mL per dose, maximum 30 mL per day
4 to 5 years	10 mL per dose, maximum 50 mL per day
6 to 8 years	10 to 15 mL per dose, maximum 65 mL per day
9 to 10 years	15 mL per dose, maximum 80 mL per day
11 to 12 years	20 mL per dose, maximum 100 mL per day

The maximum daily dose should not exceed 80 mg/kg/day for children weighing less than 37 kg.

PARAMOL may be given directly in the mouth or, if desired, it may be mixed with milk, juice or water.

Duration of treatment

This medication should not be given to children for more than 3 days without consulting a doctor.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted. The specific antidote is N-acetylcysteine.

In case of missed dose

Administer the missed dose to your child as soon as you remember unless the next intake is near. Go on giving the next scheduled dose as directed. Do not administer a double dose at once.

Contraindications

This drug is contraindicated in case of known hypersensitivity to any of the components.

Precautions

- Severe or recurrent pain or high or continued fever may indicate serious illness. If pain persists for more than 5 days, if fever gets worse or lasts for more than 3 days, if new symptoms occur or if redness or swelling is present, consult your doctor immediately.
- If sore throat is severe, persists for more than 2 days and is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor immediately.

- Consult your doctor for use in children under 2 months.
- To avoid overdose, do not administer with any other product containing paracetamol.
- This drug should be used with caution in case of severe liver or kidney disease.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently. The liver effects of paracetamol may be increased by the use of alcohol and large doses or long-term administration of the following drugs: barbiturates, carbamazepine and rifampicin

Adverse reactions

This drug is generally well tolerated when used as directed.

If a rare sensitivity reaction occurs, the drug should be discontinued.

Storage

Keep bottle tightly closed in a cool dry place below 25°C out of the reach of children. Protect from excessive heat and cold.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

PARAMOL, paracetamol 120 mg / 5 mL, bottle of 60 mL with a dosing cup

Revision date: 07/2004

PARS1/002