

PAROL[®]

CHILDREN 5-12 YEARS PARACETAMOL ELIXIR 240 mg/ 5 mL

1- DESCRIPTION:

Each 5 mL of PAROL[®] Children elixir contains 240 mg of paracetamol (Acetaminophen USP).

2- OTHER INGREDIENTS:

Glycerol, Propylene Glycol, PEG 4000, Sorbitol, Sucralose, Acesulfame Potassium, Strawberry Flavor, Berries Flavor, Red 40, Brilliant blue, Potassium Sorbate, Benzoic Acid, Purified Water.

3- INDICATIONS:

PAROL[®] Children elixir is an analgesic and antipyretic.

It relieves fever and pain associated with headache, toothache, sore throat, infections and vaccination.

4- DOSAGE:

For oral administration only.

A dose of 10-15 mg/kg to be repeated (please see table below).

Weight (Kg)	Age	Dose Volume (mL)
18-20	5-6 years	5.5
20-23	6-7 years	6
23-25	7-8 years	7
25-28	8-9 years	7.5
28-32	9-10 years	8.5
32-36	10-11 years	10
36-41	11-12 years	11

Do not give to your child more frequently than every 4 hours.

Do not give to your child more than four doses in any 24-hour period.

Do not give to your child for longer than 3 days without asking a doctor.

*Dose may be chosen based on weight or age, use weight if you know it, otherwise use age.

5- DIRECTIONS:

- Shake well before use.
- Do not exceed stated dose.

6- WARNINGS:

- Do not give if your child is sensitive to paracetamol or any other ingredient in the product.
- Do not give with any other products containing paracetamol.
- Do not use if your child has been diagnosed with liver or kidney impairment.
- If symptoms persist, seek medical advice.
- Stop using PAROL[®] If you notice allergic reactions.
- If your child has hereditary problems of fructose intolerance, he must not take PAROL[®] as it contains Sorbitol.

7- OVERDOSE:

PAROL[®] overdose may cause liver failure. Immediate medical management is required even if symptoms of overdose are not present.

Massive over dosage exceeding 10 g of paracetamol may cause liver failure. Early symptoms may include pallor, nausea, vomiting and general malaise.

Clinical and laboratory evidence of liver damage may not be apparent until 48 to 72 hours post ingestion. Overdose should be promptly treated by gastric lavage followed by intravenous N-acetylcysteine or methionine without waiting for the results of plasma paracetamol levels. General supportive measures must be available. Additional antidote therapy is normally considered in light of further plasma paracetamol levels at the time elapsed since ingestion. In all cases of suspected overdose, prompt medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

8- STORAGE CONDITIONS:

- Store below 25°C.
- Protect from light.
- Keep out of reach of children.

9- THIS IS A MEDICINE:

- Medicine is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow your doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicine.
- The doctor and pharmacist are experts in the use of medicines, their benefits and risks.
- Do not stop by yourself the period of treatment prescribed for you.
- Do not repeat the prescription without consulting your doctor.



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