



Calpol
Suspension

For relief of pain and fever in babies and infants (Analgesic /Antipyretic)

Description
Each 5ml spoonful contains 120mg paracetamol BP. Calpol has a strawberry flavour which makes it pleasant to take and easy to give to children. It contains no alcohol. A measuring spoon is included in the pack.

Other ingredients
Sucrose (White Refined Sugar), Sorbitol 70% Solution, Glycerine 98% vegetable oil, Xanthan Gum, Methyl Hydroxybenzoate, Strawberry Flavour, Carmoisine and Purified Water.

Introduction
Paracetamol is a clinically proven analgesic and antipyretic. It produces its effects by its action on central and peripheral prostaglandin synthesis inhibition.

Indication
Calpol gently relieves mild to moderate pain and fever including headache, earache/otalgia, sore throat, relief of pain and fever associated with vaccination/immunisation, respiratory tract infections including cold and flu without irritating the stomach. Calpol is suitable for children aged 1 month and above.

Dosage and administration
For oral administration only.
Always use the lowest effective dose for the shortest duration of treatment to relieve the child's symptoms.
Minimum dosing interval: 4 hours
Maximum daily dosing: 60mg/kg presented in divided doses of 10-15mg/kg throughout the 24 hour period.
Not more than 4 divided doses in any 24 hour period. Maximum duration of continued use without medical advice: 3 days.
For children under 3 months, if fever persists for >24 hours (4 doses) seek medical advice to exclude a serious infectious cause.
Post-vaccination fever in children 1 month -3 months:
A single dose of 10 - 15 mg/kg for symptomatic relief of fever following vaccination. If a second dose is required, leave at least 4 hours between doses. Medical advice should be sought if fever persists after a second dose.

Age	Weight (kg)	Dose Vol (ml)
1-6 months	4-6 kg	2.5 ml
6-12 months	6-8 kg	3.75 ml
12-24 months	8-12 kg	5.0 ml
2-5 years	12-18 kg	7.5 ml
5-8 years	18-24 kg	10.0 ml
8-10 years	24-30 kg	15.0 ml
10-12 years	30-36 kg	17.5 ml

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Contraindications
Calpol is contraindicated in patients who have hypersensitivity to paracetamol or excipients.

Special warnings and precaution for use

- Calpol contains paracetamol.
- Do not give this medicine if the child is already taking any other prescription or non prescription medicines containing paracetamol to treat pain, fever and symptoms of cold and flu or to aid sleep.
- Paracetamol overdose may cause liver failure which may require liver transplant or lead to death. Underlying liver disease increases the risk of paracetamol-related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.
- Too much paracetamol may cause serious harm to your child's liver.
- Check with your doctor before use if the child:
 1. Has a liver or kidney problem.
 2. Is underweight or malnourished .
 3. Has severe infection that may cause increased risk of metabolic acidosis. Signs of metabolic acidosis include: deep, rapid and difficult breathing, feeling sick (nausea and vomiting) and loss of appetite.

Contact a doctor immediately if your child gets a combination of these symptoms.

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

Side effects
When taken at recommended doses paracetamol is usually free from side effects. Skin reactions such as urticaria have been described rarely.

Adverse reaction
Stop administering this product and consult your child's doctor immediately if:

- You notice allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- You notice a skin rash or peeling, or mouth ulcers.
- The child previously experienced breathing problems with aspirin or non-steroidal, anti-inflammatories and experience a similar reaction with this product.
- The child experiences unexplained bruising or bleeding.
- These reactions are rare.

Overdose
In all cases of suspected overdose seek medical advice immediately even if the child does not have any symptoms because of the risk of liver failure. Paracetamol overdose may cause liver failure which may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity. Early symptoms may cause pallor, nausea, vomiting, (Diaphoresis) and general malaise. Clinical and laboratory evidence of liver damage may not be apparent until 48 hrs 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. Additional antidote therapy is normally considered in light of further plasma paracetamol levels and the time elapsed since ingestion.

Presentation
Calpol Suspension is packed in amber colored glass bottle with a child resistant cap and is available in 60ml and 100ml.

Storage conditions
Store below 30°C. Keep the bottle tightly closed.

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THIS IS A MEDICINE

- Medicines are products which affect one's health, failure to follow the instructions may be dangerous to the child.
- Follow your doctor's advice carefully and the instructions of the Pharmacist who dispensed the medicine.
- Your doctor and the pharmacist are experts in the use of medicines, its benefits and risks.
- Do not stop the course of treatment for the child early unless advised to do so by your doctor or pharmacist.
- Do not repeat the same prescription without consulting your doctor.

KEEP MEDICINE OUT OF REACH OF CHILDREN

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GSK is committed to the effective collection and management of human safety information relating to our products and we encourage healthcare professionals to report adverse events to us.

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Attention

KLD and Dimensions are only for reference and are not to be printed.

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Print Process:	Colour Standard Reference: XXX	Material Type: XXX	XXXX
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BLACK		Leading: XXX	
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