

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Calpol Baby and Infant Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml spoonful of suspension contains Paracetamol Ph.Eur. 120mg

(Paracetamol Ph.Eur. 2.40% w/v)

3. PHARMACEUTICAL FORM

Aqueous suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Calpol gently relieves pain and reduces temperature in babies and infants. It is recommended for the relief of pain and fever associated with teething, toothaches and sore throat. It also reduces feverishness in colds, influenza, childhood infections and vaccinations without irritating the stomach. Calpol is suitable 1-0 for babies and children aged 3 months to 12 years

4.2 Posology and Method of Administration

Always use the lowest effective dose 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

Calpol should not be given to infants under 3 months of age except on medical advice.

Do not give more than the stated dose.

If an excessive amount is taken contact a doctor immediately.

Age	Weight (kg)	Dose Vol (ml)
3-6 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

Wherever possible, dosing should be according to the weight of the child. If the child's weight is between two of the listed weights, always use the dose for the lower weight

For example, if the child weighs 9 kg use the dose recommended for an 8 kg child (5 mL).

4.3 Contraindications

Hypersensitivity to paracetamol or any of the other constituents

4.4 Special Warnings and Precautions for use

- Keep out of reach of children.
- If your baby was born prematurely and is less than 3 months old, consult your doctor prior to use of this product.
- Do not exceed the stated dose. If symptoms persist seek medical advice.
- Calpol contains paracetamol.
- Do not give this medicine if the child is already taking any Other Storage conditions prescription or non-prescription medicines containing paracetamol Store below 300C. Keep the bottle tightly closed. to treat pain, fever and symptoms of cold and flu or to aid sleep.
- Cause of hepatic dysfunction I failure has been reported in patients with depleted glutathione levels such as those who are severely malnourished, anorexic, have low body mass index, or are chronic heavy users of paracetamol.
- Taking too much paracetamol can cause serious harm to your 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
 4. Is taking warfarin or similar medicines used to thin blood.

4.5 Interaction with other medicinal products and other forms of interaction

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine. The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

4.6 Pregnancy and lactation

This product is intended for use in children.

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

4.7 Effects on ability to drive and use machines None

4.8 Undesirable effects

Adverse events of paracetamol from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by system class. Due to limited clinical trial data, the frequency of these adverse events is not known (cannot be estimated from available data), but post-marketing experience indicates that adverse reactions to paracetamol are rare and serious reactions are very rare.

Post marketing data

Body System	Undesirable effect
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis

Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes, angiodema and Stevens Johnson syndrome/toxic epidermal necrolysis
Respiratory, thoracic and mediastinal disorders	Bronchospasm*
Hepatobiliary disorders	Hepatic dysfunction

* There have been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.

4.9 Overdose

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk Factors:

If the patient

- Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

Or

- Regularly consumes ethanol in excess of recommended amounts. Or
- Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms

Symptoms of paracetamol overdose in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4

hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol; however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous Nacetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol has analgesic and antipyretic actions. It is only a weak inhibitor of prostaglandin biosynthesis, although there is some evidence to suggest that it may be more effective against enzymes in the CNS than those in the periphery. This fact may partly account for its ability to reduce fever (a central action) and to induce analgesia.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Concentration in plasma generally reaches a peak in 20-30 minutes; plasma half-life is 1-4 hours. Paracetamol is relatively uniformly distributed throughout most body fluids. Plasma binding is variable. Excretion is almost exclusively renal in the form of conjugates.

5.3 Preclinical safety data **Not applicable**

6. PHARMACEUTICAL PARTICULARS

5.1 List of excipients

White Refined Sugar, Sorbitol Solution 70%, Glycerin Vegetable Grade, Xanthan gum (Xantural 180), Methyl Hydroxybenzoate, Carmoisine Eurocert 800804, Strawberry flavor 500018E, Purified water.

5.2 Incompatibilities None

5.3 Shelf life

36 months

5.4 Special precautions for storage

To be stored below 30°C

5.5 Nature and contents of container

Amber glass bottle, type III glass of 60mL fitted with white tamper proof child resistant senior friendly closure. The bottle is packed into a cardboard carton accompanied by a 5 ml plastic measuring spoon and a patient information leaflet.

5.6 Special precautions for disposal None

7. MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Limited Likoni

Road, Nairobi Kenya

Likoni road P.O.Box 78392

+254206933200

+254206933385

Nairobi Kenya

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

N/A

10. DATE OF REVISION OF THE TEXT

30th August 2016