SUMMARY OF PRODUCT CHARACTERISTICS

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1 NAME OF THE MEDICINAL PRODUCT

Calpol Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml spoonful of suspension contains Paracetamol BP 120mg

3 PHARMACEUTICAL FORM

Aqueous suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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.

4.2 Posology and Method of Administration

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) medical advice should be sought 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.

Not recommended in children under 1 month.

Do not give more than the stated dose.

If an excessive amount is taken a doctor should be contacted immediately.

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

Wherever possible, dosing should be according to the weight ofthe child. If the child's weight is between two of the listed weights, always use the dose for the lower weight e.g., if the child weighs 9 kg use the dose recommended for an 8 kg child (5 mL).

If you are uncertain about the child's weight then use the dose which is suitable for your child's age, for example if the child is 18 months old, a dose of 5 ml should be used.

4.3 Contraindications

Hypersensitivity to paracetamol or any of the other constituents

4.4 Special Warnings and Precautions 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 the liver.
- Do not exceed the stated dose.
- Seek medical advice before giving the product 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.
- Keep out of reach of children.
- Cases of hepatic dysfunction have 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 alcohol.

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. Very rare cases of serious skin reactions have been reported.
Respiratory, thoracic and mediastinal disorders	Bronchospasm*
Hepatobiliary disorders	Hepatic dysfunction

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Paracetamol overdose may cause liver failure which can lead to liver transplant or death. Acute pancreatitis has been observed usually with hepatic dysfunction and liver toxicity. There is a risk of poisoning with paracetamol particularly in elderly subjects, young children, patients with liver disease, cases of chronic alcoholism and in patients with chronic malnutrition. Overdosing may be fatal in these cases.

Some patients may be at increased risk of liver damage from paracetamol toxicity.

Risk Factors include:

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 transfer to hospital

Blood sampling to determine initial paracetamol plasma concentration. In the case of a single acute overdose, paracetamol plasma concentration should be measured 4 hours post ingestion.

Administration of activated charcoal should be considered if >150mg/kg paracetamol has been taken within 1 hour.

The antidote N-acetylcysteine should be administered as soon as possible in accordance with National treatment guidelines Symptomatic treatment should be implemented.

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

Preclinical safety data on paracetamol in the literature have not revealed any pertinent and conclusive findings which are of relevance to the recommended dosage and use of the product and which have not been mentioned elsewhere in this Summary.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White Refined Sugar,

Sorbitol Solution 70%,

Glycerin 98% Vegetable oil,

Xanthan gum,

Methyl Hydroxybenzoate,

Carmoisine,

Strawberry flavor,

Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

To be stored below 30ºC

6.5 Nature and contents of container

Amber glass bottle, type III glass of 60mL or 100ml 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.

6.6 Special precautions for disposal

No Special requirements

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

Certificate No: 07276/07371/VAR/2021

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Apr 13, 2022

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