

SUMMARY OF PRODUCT CHARACTERISTICS.

This information is intended for use by health professionals

1.Name of the medicinal product

Acimol suspension.

2.Qualitative and quantitative composition

Acimol Suspension contains 120mg Paracetamol in each 5ml.

Excipients: sorbitol liquid contains 2.25g of sorbitol liquid per 5ml), Sodium methyl paraben and Sodium propyl paraben.

For the full list of excipients, see section 6.1.

3.Pharmaceutical form

Oral Suspension

A pink homogenous suspension

4.Clinical particulars

4.1 Therapeutic indications

Acimol Suspension is indicated for the treatment of mild to moderate pain and as an antipyretic. It can be used in many conditions including headache, toothache, earache, teething, sore throat, colds & influenza, aches and pains and post-immunization fever.

4.2 Posology and method of administration

For the relief of fever after vaccinations at 2, 3 and 4 months

2.5ml. This dose may be given up to 4 times a day starting at the time of vaccination. Do not give more than 4 doses in any 24 hour period. Leave at least 4 hours between doses. If your baby still needs this medicine two days after receiving the vaccine talk to your doctor or pharmacist.

Age: 2 – 3 months	Dose
Pain and other causes of fever - if your baby weighs over 4 kg and was born after 37 weeks	2.5 ml If necessary, after 4-6 hours, give a second 2.5 ml dose
• Do not give to babies less than 2 months of age. • Leave at least 4 hours between doses. • Do not give more than 2 doses. This is to ensure that fever that may be due to a serious infection is quickly diagnosed. If your child is still feverish after two doses, talk to your doctor or pharmacist.	

Children aged 3 months – 6 years:

Child's Age	How Much	How often (in 24 hours)
3 – 6 months	2.5 ml	4 times
6 – 24 months	5 ml	4 times
2 – 4 years	7.5 ml (5 ml + 2.5 ml)	4 times
4 – 6 years	10 ml (5 ml + 5 ml)	4 times

- Do not give more than 4 doses in any 24-hour period
- Leave at least 4 hours between doses
- Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist

It is important to **shake the bottle** for at least 10 seconds before use.

The Elderly:

In the elderly, the rate and extent of paracetamol absorption is normal but plasma half-life is longer and paracetamol clearance is lower than in young adults.

4.3 Contraindications

Hypersensitivity to paracetamol or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Do not exceed the recommended dose. Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help straight away. Quick medical attention is critical for adults as well as children even if signs or symptoms are not noticed.

Taking this product with other paracetamol-containing medicines could lead to overdose and should therefore be avoided.

Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment.

The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Chronic alcohol users should consult a doctor before use.

Sorbitol may cause gastrointestinal discomfort and have a mild laxative effect. Each 5 ml of this product contains 0.45 g sorbitol liquid. It has a calorific value of 2.6 kcal/g sorbitol.

Due to the presence of sorbitol liquid, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption should not take this medicine.

Propyl and Methyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

Patients should be informed about the signs of serious skin reactions and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.

As with all medicines, if your child is currently taking any other medicine consult your doctor or pharmacist before using this product.

Keep out of the sight and reach of children.

Do not store above 30°. Keep bottle in the outer carton.

It is important to shake the bottle for at least 10 seconds before use.

Talk to a doctor at once if your child takes too much of this medicine, even if they seem well.

The leaflet contains the following statements:

Talk to a doctor at once if your child takes too much of this medicine, even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage.

Very rare cases of serious skin reactions have been reported. Symptoms may include:

- Skin reddening
- Blisters
- Rash

If skin reactions occur or existing skin symptoms worsen, stop use and seek medical help right away.

4.5 Interaction with other medicinal products and other forms of interaction Drugs which induce hepatic microsomal enzymes

Metabolism of paracetamol possibly accelerated by carbamazepine, fosphenytoin, phenytoin, phenobarbital, primidone (also isolated reports of hepatotoxicity).

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine.

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.

Chronic alcohol intake can increase the hepatotoxicity of paracetamol overdose and may have contributed to the acute pancreatitis reported in one patient who had taken an overdose of paracetamol. Acute alcohol intake may diminish an individual's ability to metabolise large doses of paracetamol, the plasma half-life of which can be prolonged.

4.6 Fertility, pregnancy and lactation Pregnancy

A large amount of data on pregnant women indicate neither malformative, nor fetotoxicity. Paracetamol can be used during pregnancy if clinically needed however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

When given to the mother in therapeutic doses (1 g single dose), paracetamol crosses the placenta into foetal circulation as early as 30 minutes after ingestion and is metabolised in the foetus by conjugation with sulfate and increasingly with glutathione.

Breast-feeding

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast-feeding.

Fertility

There is no information relating to the effects of Calpol Infant Suspension on fertility.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse drug reactions (ADRs) identified during clinical trials and post-marketing experience with paracetamol are listed below by System Organ Class (SOC).

The frequencies are defined according to the following

convention: Very common $\geq 1/10$

Common $\geq 1/100$ to $< 1/10$

Uncommon $\geq 1/1,000$ to $< 1/100$

Rare $\geq 1/10,000$ to $< 1/1,000$

Very rare $< 1/10,000$

Not known (cannot be estimated from available data).

ADRs are presented by frequency category based on 1) incidence in adequately designed clinical trials or epidemiology studies, if available or 2) when incidence is unavailable, frequency category is listed as Not known.

System Organ Class (SOC)	Frequency	Adverse Drug Reaction (Preferred Term)
Blood and lymphatic system disorders	Not known	Blood disorder (including thrombocytopenia and agranulocytosis) ¹
Immune System Disorders	Very rare Very rare	Anaphylactic reaction Hypersensitivity
Hepatobiliary disorders	Not known	Liver injury ²
Skin and Subcutaneous Tissue disorders	Very rare Not known Not known	Rash Rash pruritic Urticaria
Renal and urinary disorders	Uncommon Not known	Nephropathy toxic Renal papillary necrosis ³
Investigations	Not known	Transaminases increased ⁴

¹ Reported following paracetamol use, but not necessarily causally related to the drug

² Chronic hepatic necrosis has been reported in a patient who took daily therapeutic doses of paracetamol for about a year

³ Reported after prolonged administration

⁴ Low level transaminase elevations may occur in some patients taking therapeutic doses of paracetamol; these elevations are not accompanied with liver failure and usually resolve with continued therapy or discontinuation of paracetamol.

Very rare cases of serious skin reactions have been reported.

Chronic hepatic necrosis has been reported in a patient who took daily therapeutic doses of paracetamol for about a year and liver damage has been reported after daily ingestion of excessive amounts for shorter periods. A review of a group of patients with chronic active hepatitis failed to reveal differences in the abnormalities of liver function in those who were long-term users of paracetamol nor was the control of the disease improved after paracetamol withdrawal.

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 Pharmacovigilance Electronic Reporting System (PvERS) <https://pv.pharmacyboardkenya.org/>

4.9 Overdose

Liver damage is possible in adults and adolescents (≥ 12 years of age) who have taken 7.5g or more of paracetamol. It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested) become irreversibly bound to liver tissue. 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

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

OR

b) Regularly consumes ethanol in excess of recommended amounts OR

c) Is likely to be glutathione deplete e.g, eating disorders, cystic fibrosis, HIV infection, starvation, cachexia

Symptoms

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, hyperhidrosis, malaise, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. This may include hepatomegaly, liver tenderness, jaundice, acute hepatic failure and hepatic necrosis. Abnormalities of glucose metabolism and metabolic acidosis may occur. Blood bilirubin, hepatic enzymes, INR, prothrombin time, blood phosphate and blood lactate may be increased. 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.

Haemolytic anaemia (in patients with glucose-6-phosphate dehydrogenase [G6PD] deficiency): Haemolysis has been reported in patients with G6PD deficiency, with use of paracetamol in overdose.

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 the 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 concentrations 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 N-acetylcysteine, 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 patient 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

Pharmacotherapeutic group: Other Analgesics and Antipyretics

(Anilides) ATC Code: N02 BE01

Paracetamol has analgesic and antipyretic effects that do not differ significantly from those of aspirin. However it has only weak anti-inflammatory effects. It is only a weak inhibitor of prostaglandin biosynthesis although there is some evidence to suggest it may be more effective against enzymes in the central nervous system than in the periphery. This may in part account for its activity profile.

5.2 Pharmacokinetic properties Absorption

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract with peak plasma concentrations occurring 0.5-2 hours after dosing. The plasma half-life is approximately 2 hours after therapeutic doses in adults but is increased in neonates to about 5 hours.

Distribution

It is widely distributed through the body.

Biotransformation

Metabolism is principally by the hepatic microsomal enzymes and urinary excretion accounts for over 90% of the dose within 1 day. Virtually no paracetamol is excreted unchanged, the bulk being conjugated with glucuronic acid (60%), sulphuric acid (35%) or cysteine (3%).

Children have less capacity for glucuronidation of the drug than adults.

Elimination

Following therapeutic doses 90-100% of the drug is recovered in the urine within 24 hours.

5.3 Preclinical safety data Mutagenicity

There are no studies relating to the mutagenic potential of Acimol Suspension.

In vivo mutagenicity tests of paracetamol in mammals are limited and show conflicting results. Therefore, there is insufficient information to determine whether paracetamol poses a mutagenic risk to man.

Paracetamol has been found to be non-mutagenic in bacterial mutagenicity assays, although a clear clastogenic effect has been observed in mammalian cells *in vitro* following exposure to paracetamol (3 and 10 mM for 2h).

Carcinogenicity

There are no studies to the carcinogenic potential of CALPOL Infant Suspension.

There is inadequate evidence to determine the carcinogenic potential of paracetamol in humans. A positive association between the use of paracetamol and cancer of the ureter (but not of other sites in the urinary tract) was observed in a case-control study in which approximate lifetime consumption of paracetamol (whether acute or chronic) was estimated. However, other similar studies have failed to demonstrate a statistically significant association between paracetamol and cancer of the urinary tract, or paracetamol and renal cell carcinoma.

There is limited evidence for the carcinogenicity of paracetamol in experimental animals. Liver cell tumours can be detected in rats following chronic feeding of 500 mg/kg/day paracetamol.

Teratogenicity

There is no information relating to the teratogenic potential of CALPOL Infant Suspension. In humans, paracetamol crosses the placenta and attains concentrations in the foetal circulation similar to those in the maternal circulation. Intermittent maternal ingestion of therapeutic doses of paracetamol are not associated with teratogenic effects in humans.

Paracetamol has been found to be foetotoxic to cultured rat embryo.

Fertility

A significant decrease in testicular weight was observed when male Sprague-Dawley rats were given daily high doses of paracetamol (500 mg/kg/body weight/day) orally for 70 days.

6. Pharmaceutical particulars

6.1 List of excipients

Xanthan gum

Glycerin

Sorbital 70%
solution

Sodium saccharin

Sodium methyl
paraben Sodium

propyl paraben

Citric acid

Erythrosine soluble

colour
Strawberry flavour
Bronopol
Purified water.

6.2 Incompatibilities

None known

6.3 Shelf life

36 years

6.4 Special precautions for storage

Do not store above
30°C.

Store in a dry place.

Protect from direct sunlight

Keep away from the reach of children.

6.5 Nature and contents of

container Amber glass/pet

bottles in unit boxes Pack sizes

:100ml and 60ml

6.6 Special precautions for disposal and other handling

No special requirements for disposal

7. Marketing authorisation holder

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8. Marketing authorisation number(s)

H2021/CTD8701/16593

9. Date of first authorisation/renewal of the authorisation

2021 September 01

10. Date of revision of the text

22/08/2026