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**Adverse events should also be reported to  
McNeil Products Limited on 0808 238 9999.**

## **CALPOL Infant Original 120mg/5ml Oral Suspension (paracetamol), Calpol Sugar Free Infant Suspension (incl. Sachets) (paracetamol) Product Information**

### **Presentation:**

A pink strawberry-flavoured suspension containing 120 mg paracetamol per 5 ml.

### **Uses:**

Treatment of mild to moderate pain and as an antipyretic. Can be used in many conditions including headache, toothache, earache, teething, sore throat, colds and influenza, aches and pains and post immunisation fever.

### **Dosage:**

*For the relief of fever after vaccinations at 2, 3 and 4 months:* 2.5 ml up to 4 times a day starting at the time of vaccination. If your baby still needs this medicine two days after receiving the vaccine talk to your doctor or pharmacist.

*Dosage for the relief of pain and other causes of fever in babies aged 2 to 3 months, if your baby weighs over 4 kg, and was born after 37 weeks):* 2.5 ml. If necessary, give a second dose after 4 to 6 hours.

*Dosage for children 3 to 6 months:* 2.5 ml; *children 6 to 24 months:* 5 ml; *children 2 to 4 years:* 7.5 ml; *children 4 to 6 years:* 10 ml.

Shake the bottle for at least 10 seconds before use. For CALPOL Sugar Free Infant Suspension Sachets, massage the sachet before use. Do not give more than 4 doses in 24 hours. Leave at least 4 hours between doses.

### **Contraindications:**

This product is contraindicated in patients with hypersensitivity to paracetamol or to any excipients of this product. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take CALPOL Infant Original 120mg/5ml Oral Suspension due to the presence of sucrose and sorbitol liquid (E420). Meanwhile, patients with rare hereditary problems of fructose intolerance should not take CALPOL Sugar Free Infant Suspension (incl. Sachets) due to the presence of maltitol liquid (E965) and sorbitol liquid (E420).

### **Precautions:**

Taking more than the recommended doses of CALPOL Infant Original 120mg/5ml Oral Suspension and CALPOL Sugar Free Infant Suspension (incl. Sachets) products may cause liver damage. Concurrent intake of this product with other paracetamol-containing medicines can also lead to overdose and should therefore be avoided. Caution is advised in the use of this product in patients with severe hepatic impairment, or severe renal impairment, and chronic alcohol use. Cases of

high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment, sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g., chronic alcoholism) who were treated with paracetamol at therapeutic doses for prolonged periods, or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, discontinue paracetamol immediately and close monitoring is recommended. Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.

Sorbitol and maltitol may have a mild laxative effect. The latter excipient is present in the CALPOL Sugar Free Infant Suspension (incl. Sachets) products only. CALPOL Infant Original 120mg/5ml Oral Suspension and CALPOL Sugar Free Infant Suspension (incl. Sachets) products contain ethyl (E214), propyl (E216), and methyl (E218) parahydroxybenzoate, as well as carmoisine (E122), all of which may cause allergic reactions. These products also contain propylene glycol (E1520). Caution in babies less than 4 weeks old as co-administration with any substrate for alcohol dehydrogenase, such as ethanol, may induce serious adverse effects in neonates. CALPOL Sugar Free Infant Suspension (incl. Sachets) products contain benzyl alcohol, which may cause allergic reactions. It has been linked with the risk of severe side effects including breathing problems ("gasping syndrome") in young children. Caution should be taken in newborn babies up to 4 weeks old and in children under 3 years. Do not use for more than 1 week due to increased risk due to accumulation. If the patient is pregnant or breastfeeding, or if the patient has kidney or liver disease, large amounts of benzyl alcohol can build up (metabolic acidosis). 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. CALPOL Infant Original 120mg/5ml Oral Suspension and CALPOL Sugar Free Infant Suspension (incl. Sachets) products contain less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'. Paracetamol has known interactions with domperidone, metoclopramide, cholestyramine, warfarin and other coumarins, alcohol, other drugs that induce hepatic microsomal enzymes, carbamazepine, fosphenytoin, phenytoin, phenobarbital, primidone (also isolated reports of hepatotoxicity), and flucloxacillin.

#### **Pregnancy and Lactation:**

This product should not be used in pregnancy unless benefits to the mother outweigh risk to foetus. It should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency. In therapeutic doses (1 g single dose), paracetamol crosses the foetal circulation through the placenta as early as 30 minutes from ingestion and undergoes metabolism by conjugation with sulphate and increasingly with glutathione. Paracetamol is excreted in breast milk in low concentrations; however, available published data do not contraindicate breastfeeding

#### **Side effects:**

Uncommon: nephropathy toxic.

Very rare: anaphylactic reaction, hypersensitivity, rash.

Not known: blood disorder (including thrombocytopenia and agranulocytosis), liver injury, fixed eruption, rash pruritic, urticaria, renal papillary necrosis, and transaminases increased, high anion gap metabolic acidosis.

Chronic hepatic necrosis has been reported.

*Please refer to Summary of Product Characteristics for detailed information.*

**RRP (ex-VAT):** CALPOL Infant Original 120 mg/5 ml Oral Suspension 100 ml bottle

(GSL): £4.13; CALPOL Infant Original 120 mg/5 ml Oral Suspension 200 ml bottle (P): £6.83; Calpol Sugar Free Infant Suspension 100 ml bottle (GSL): £4.13; CALPOL Sugar Free Infant Suspension 200 ml bottle (P): £6.83; CALPOL Sugar Free Infant Suspension Sachets 12 x 5 ml sachets (GSL): £4.41; CALPOL Sugar Free Infant Suspension Sachets 20 x 5 ml sachets (GSL): £7.00

**Legal category:** CALPOL Infant Original 120 mg/5 ml Oral Suspension 100 ml bottle: GSL; CALPOL Infant Original 120 mg/5 ml Oral Suspension 200 ml bottle: P; Calpol Sugar Free Infant Suspension 100 ml bottle: GSL; CALPOL Sugar Free Infant Suspension 200 ml bottle: P; CALPOL Sugar Free Infant Suspension Sachets: GSL

**PL Holder:** McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG

**PL Numbers:**

CALPOL Infant Original 120 mg/5 ml Oral Suspension 100ml bottle (GSL): 15513/0122; CALPOL Infant Original 120 mg/5 ml Oral Suspension 200 ml bottle (P): 15513/0004; Calpol Sugar Free Infant Suspension 100ml bottle (GSL): 15513/0123; CALPOL Sugar Free Infant Suspension 200 ml bottle (P): 15513/0006; CALPOL Sugar Free Infant Suspension Sachets (GSL): 15513/0155

**Date of prep:** 20 MAR 2025

## **CalCough Infant Syrup (glycerol) Product Information:**

**Presentation:**

Syrup containing 0.75ml glycerol per 5ml (15%v/v).

**Uses:**

Relief of dry tickly coughs.

**Dosage:**

*Children aged 1–5 years:* two 5ml spoonfuls (or 10ml) given three to four times daily;

*Children 3 months to 1 year:* one 5ml spoonful given three to four times daily;

*Children under 3 months:* not recommended.

**Contraindications:**

Hypersensitivity to ingredients; fructose intolerance.

**Precautions:**

Diabetics should take note that glycerol may affect blood sugar levels. If symptoms persist for more than 3 days or get worse, patients should stop use and consult a doctor. This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'. This medicine also contains 10 mg sodium benzoate (E 211) in each 5 ml, which is equivalent to 2 mg/ml, and 18.24 mg propylene glycol (E 1520) in each 5 ml, which is equivalent to 3.65 mg/ml.

**Pregnancy and Lactation:**

Not applicable.

**Side Effects:**

Possible mild laxative effect.

*Please refer to Summary of Product Characteristics for detailed information.*

**RRP (ex-VAT):** 125ml: £4.41

**Legal Category:** GSL

**PL Holder:** McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG

**PL Number:** 15513/0168

**Date of prep:** 28 Nov 2024