

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

**Adverse events should also be reported to
McNeil Products Limited on 01344 864 042.**

CALPOL Infant Original 120mg/5ml Oral Suspension, Calpol Sugar-Free Infant Suspension (incl. Sachets) (Paracetamol)

Product Information:

Presentation:

Suspension containing 120mg Paracetamol per 5ml

Indication:

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 and Administration:

For the relief of fever after vaccinations at 2,3 and 4 months; 2.5ml 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 2-3 months (if your baby weighs over 4kg and was born after 37 weeks); 2.5ml. If necessary give a second dose after 4-6 hours. Dosage for Children over 3 months; Children 3 to 6 months: 2.5 ml. Children 6 to 24 months: 5 ml. Children 2 years to 4 years: 7.5 ml. Children 4 to 6 years: 10ml. Do not give more than 4 doses in 24 hours and leave at least 4 hours between doses.

Contraindications:

Hypersensitivity to paracetamol or other ingredients.

Precautions:

Do not exceed recommended dose or take with other paracetamol-containing medicines. Caution in severe hepatic or renal impairment and chronic alcohol use. Interactions with domperidone, metoclopramide, cholestyramine, anticoagulants, alcohol, drugs that induce hepatic microsomal enzymes, carbamazepine, fosphenytoin, phenytoin, phenobarbital, and primidone (also isolated reports of hepatotoxicity). Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risk factors. Due to the presence of sucrose and sorbitol in the Infant Suspension, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine. Due to the presence of maltitol liquid and sorbitol liquid in the Sugar Free Suspension, patients with rare hereditary problems of fructose intolerance should not take this medicine. Sorbitol and maltitol (Sugar-Free only) may have a mild laxative effect. Parahydroxybenzoates and carmoisine may cause allergic reactions. 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. Benzyl alcohol (Sugar-Free only) may cause allergic reactions. Large amounts of benzyl alcohol can build-up in your body and may cause metabolic acidosis. Benzyl alcohol has been linked with the risk of severe side

effects including breathing problems (“gasping syndrome”) in young children. Caution in newborn babies (up to 4 weeks old). Caution in children under 3 years old; do not use for more than 1 week due to increased risk due to accumulation. 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.

Fertility, pregnancy and lactation: Consult doctor before use.

Side effects:

Uncommon: nephropathy toxic.

Very rare: hypersensitivity, anaphylactic reactions and rash.

Not Known: blood disorder (including thrombocytopenia and agranulocytosis), liver injury, fixed eruption, rash pruritic, urticaria, renal papillary necrosis, and transaminases increased.

Very rare cases of skin reactions. Chronic hepatic necrosis has been reported.

RRP (ex-VAT): 60ml bottle (sugar free only): £2.49; 100ml bottle: £3.96; 200ml bottle: £6.56; 12 x 5ml sachets (sugar free only): £4.23; 20 x 5ml sachets (sugar free only): £6.72

Legal category: 200ml bottle: P; 100ml bottle: GSL; 60ml bottle (sugar free only): GSL; Sachets (Sugar-free only): GSL

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

PL Numbers: CALPOL Infant Original 120mg/5ml Oral Suspension: 100ml bottle: 15513/0122; 200ml bottle: 15513/0004; Calpol Sugar-free Infant Suspension: 60ml and 100ml bottle: 15513/0123; 200ml bottle: 15513/0006; Sachets: 15513/0155

Date of Preparation: 18 January 2023