

**Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)**

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

## **Calpol Infant Sugar Free Colour Free 120mg/5ml Oral Suspension (Paracetamol) Product Information:**

### **Presentation:**

Suspension containing 120mg paracetamol per 5ml.

### **Indications:**

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 aged 3–6 months: 2.5ml. Children 6–24 months: 5ml. Children 2–4 years: 7.5ml. Children 4–6 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:**

Caution in severe hepatic or renal impairment and chronic alcohol use. Do not exceed recommended dose. Concomitant use of other paracetamol-containing products should be avoided. 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.

Patients with rare hereditary problems of fructose intolerance should not take this medicine. Sorbitol and maltitol may have a mild laxative effect.

Parahydroxybenzoates may cause allergic reactions. 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. 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 may cause allergic reactions. Large amounts of benzyl alcohol can build-up in the body and may cause metabolic acidosis if patients are pregnant or

breastfeeding, or have a liver or kidney disease. 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.

**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):** 100ml bottle: £3.96

**Legal category:** GSL

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

**PL Numbers:** 15513/0300.

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