

Product Information for Calpol Infant Sugar Free Colour Free 120mg/5ml Oral Suspension, CALPOL Infant Original 120mg/5ml Oral Suspension, Calpol Sugar-Free Infant Suspension (incl. Sachets), Calpol Six Plus Sugar Free Suspension, Calpol Six Plus Suspension Sugar Free and Calpol Six Plus Fastmelts

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/>

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 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:

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: £3.83

Legal category: GSL

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

PL Numbers: 15513/0300.

Date of Preparation: 29 JUNE 2022

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

Calpol Six Plus Sugar Free Suspension (Paracetamol) and Calpol Six Plus Suspension Sugar Free (Paracetamol) Product Information:

Presentation:

Suspension containing 250mg paracetamol per 5ml.

Indications:

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

Dosage and Administration:

Adults and Children over 16 years: 10 ml to 20 ml; *Children 12-16 years:* 10 ml to 15 ml;

Children 10 to 12 years: 10 ml; *Children 8 to 10 years:* 7.5 ml; *Children 6 to 8 years:* 5 ml; *Children under 6 years:* not recommended. Do not give more than 4 doses in 24 hours. Leave at least 4 hours between doses.

Contraindications:

Hypersensitivity to paracetamol or other ingredients.

Precautions:

Taking more than the recommended dose (overdose) may cause liver damage. Caution in severe hepatic or renal impairment and chronic alcohol use. Do not dilute. Patients with rare hereditary problems of fructose intolerance should not take this medicine. Do not take with other paracetamol containing medicines. Parahydroxybenzoates may cause allergic reactions (possibly delayed). Interaction 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. Sorbitol and maltitol may have a mild laxative effect. Benzyl alcohol may cause allergic reactions. If patient is pregnant or breastfeeding, or if patient has kidney or liver disease, large amounts of benzyl alcohol can build up (metabolic acidosis). Contains propylene glycol. 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. See relevant Summary of Product Characteristics (SmPC) for full details.

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, rash pruritic, urticaria, fixed eruption, renal papillary necrosis, and transaminases increased.

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

RRP (ex-VAT):

Six Plus Sugar Free Suspension, 100ml bottle, £4.58, 200ml bottle, £7.49, 12 x 5ml sachets, £4.91; Six Plus Suspension Sugar Free, 80 ml bottle £4.08

Legal category Six Plus Sugar Free Suspension 100ml and 200ml bottle: P; Sachets: GSL and Six Plus Suspension Sugar Free 80 ml bottle: GSL.

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

PL Numbers: Six Plus Sugar Free Suspension 100 ml and 200 ml bottles & sachets: 15513/0003, Six Plus Suspension Sugar Free 80 ml bottle 15513/0164.

Date of Preparation: 29 June 2022

Calpol Six Plus Fastmelts (Paracetamol) Product Information:

Presentation:

Orodispersible tablet containing 250mg paracetamol.

Indications:

Treatment of mild to moderate pain and as an antipyretic, including headache, toothache, earache, sore throat, colds and influenza, aches and pains and post-immunisation fever. **Dosage and Administration:**

Tablets should be placed in the mouth to melt on tongue. *Adults and children over 16 years:*

2-4 tablets; children 12-16 years: 2-3 tablets; children 9-12 years: 2 tablets; children 6-9 years: 1 tablet. Under 6 years: Not recommended. Repeat dose every 4 to 6 hours if necessary, up to 4 doses in 24 hours.

Contraindications:

Hypersensitivity to ingredients.

Precautions:

Severe hepatic or severe renal impairment; interactions with domperidone, metoclopramide, cholestyramine, anticoagulants, alcohol, drugs that induce hepatic microsomal enzymes such as carbamazepine, fosphenytoin, phenytoin, phenobarbital and primidone. 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. The phenylalanine in the tablets may be harmful to people with phenylketonuria. Contains 0.0011g of glucose in each tablet. Patients with rare glucose-galactose malabsorption should not take this medicine. Contains 0.00064mg benzyl alcohol in each tablet. Benzyl alcohol may cause allergic reactions. Large amounts of benzyl alcohol can build-up in body and may cause side effects (called "metabolic acidosis"). Contains mannitol which may have a mild laxative effect. The use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity. Do not use any other paracetamol containing products whilst using this product.

Fertility, pregnancy and lactation:

Consult doctor before use.

Side effects:

Uncommon: Nephropathy toxic.

Very rare: Anaphylactic reactions, hypersensitivity and rash.

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

Very rare cases of serious skin reactions have been reported. A case of chronic hepatic necrosis has been reported.

RRP (ex-VAT): 12s £4.72; 24s £7.43

Legal cat: 12s: **GSL**, 24s: **P**

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

PL Numbers: 12s: 15513/0121, 24s: 15513/0082

Date of Preparation: 29/06/2022