

Product Information for CALPOL Infant Sugar Free Colour Free 120mg/5ml Oral Suspension (paracetamol), CALPOL Infant Original 120mg/5ml Oral Suspension (paracetamol), Calpol Sugar Free Infant Suspension (incl. Sachets) (paracetamol), Calpol Six Plus Sugar Free Suspension (paracetamol), Calpol Six Plus Suspension Sugar Free (paracetamol), Calpol Six Plus Fastmelts (paracetamol), Calprofen 100mg/5ml Oral Suspension Ibuprofen and Calprofen Ibuprofen Suspension, CalCough Infant Syrup (glycerol), CalCough Children's Syrup (glycerol, sucrose), and CALGEL TEETHING GEL (lidocaine hydrochloride monohydrate, cetylpyridinium chloride)

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 freephone 0808 238 9999.

Calpol Infant Sugar Free Colour Free 120mg/5ml Oral Suspension (paracetamol) Product Information

Presentation:

An off-white 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 aged 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. 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 should not take this medicine due to the presence of maltitol liquid

(E965) and sorbitol liquid (E420).

Precautions:

Taking more than the recommended dose of Calpol Infant Sugar Free Colour Free 120mg/5ml Oral Suspension 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. Propyl (E216) and methyl (E218) parahydroxybenzoate may cause allergic reactions which may be possibly delayed. This medicine contains 14.32 mg propylene glycol (E1520) in each 5 ml dose, or 2.86 mg/ml. 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. This product contains 0.16 mg benzyl alcohol per 5 ml, or 0.03 mg/ml. Benzyl alcohol may also cause allergic reactions. It has also been linked with 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 this product for more than 1 week due to increased risk of benzyl alcohol 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. 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). It also contains 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 reactions, 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): 100 ml bottle: £4.13

Legal category: GSL

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

PL Number: 15513/0300.

Date of prep: 20 MAR 2025

CALPOL Infant Original 120 mg/5 ml 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 (“gaspings 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

Calpol Six Plus Sugar Free Suspension (paracetamol) and Calpol Six Plus Suspension Sugar Free (paracetamol) Product Information

Presentation:

An oral suspension containing 250 mg paracetamol per 5 ml.

Uses:

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:

Adults and children over 16 years: 10 ml to 20 ml (two to four 5 ml doses) up to 4 times a day; *Children 12 to 16 years:* 10 ml to 15 ml (two to three 5 ml doses) up to 4 times a day; *Children 10 to 12 years:* 10 ml (two 5 ml doses), 4 times a day; *Children 8 to 10 years:* 7.5 ml (5 ml + 2.5 ml), 4 times a day; *Children 6 to 8 years:* 5 ml, 4 times a day; *Children under 6 years:* not recommended.

Do not give more than 4 doses in 24 hours and leave at least 4 hours between doses.

Contraindications:

This product is contraindicated in patients with hypersensitivity to paracetamol or to any of the excipients of this product. Patients with rare hereditary problems of fructose intolerance should not take this medicine due to the presence of maltitol liquid (E965) and sorbitol liquid (E420).

Precautions:

Taking more than the recommended dose of Calpol Six Plus Sugar Free Suspension or Calpol Six Plus Suspension Sugar Free 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, severe renal impairment, or 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 dilute this product. 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. Propyl (E216) and methyl (E218) parahydroxybenzoate may cause allergic reactions which may be possibly delayed. Benzyl alcohol may also 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. 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). This product contains 20.92 mg propylene glycol (E1520) in each 5ml dose. It also contains 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, 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): Six Plus Sugar Free Suspension, 100ml bottle, £4.92, 200ml bottle, £8.08, 12 x 5ml sachets, £5.29; Six Plus Suspension Sugar Free, 80 ml bottle £4.41

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

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

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 prep: 20 MAR 2025

Calpol Six Plus Fastmelts (paracetamol) Product Information

Presentation:

Round, white, bi-convex orodispersible tablet containing 250 mg paracetamol.

Uses:

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:

Adults and children over 16 years: 2 to 4 tablets; Children 12 to 16 years: 2 to 3 tablets; Children 9 to 12 years: 2 tablets; Children 6 to 9 years: 1 tablet. Children under 6 years: Not recommended.

Tablets should be placed in the mouth to melt on tongue. Do not give more than 4 doses in 24 hours. Leave at least 4 hours between doses. Repeat dose every 4 to 6 hours if necessary.

Contraindications:

This product is contraindicated in patients with hypersensitivity to paracetamol or to any of the excipients of this product. This product contains 8 mg aspartame, which is a source of phenylalanine equivalent to 0.04 mg/250 mg tablet. The phenylalanine in the tablets may be harmful to people with phenylketonuria. It also contains 0.0011 g of glucose; therefore, patients with rare hereditary problems of glucose-galactose malabsorption should not take this medicine.

Precautions:

Taking more than the recommended dose of Calpol Six Plus Fastmelts 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, severe renal impairment, or 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. This product contains mannitol, which may have a mild laxative effect. It also contains 0.00064 mg benzyl alcohol in each tablet. Benzyl alcohol may cause allergic reactions. If the patient is pregnant or breastfeeding, or if the patient has kidney or liver disease, large amounts of benzyl alcohol can build up, resulting in 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. 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 reactions, hypersensitivity, rash.

Not known: blood disorder (including thrombocytopenia and agranulocytosis), liver injury, fixed eruption, rash pruritic, urticaria, renal papillary necrosis, 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): 12s £4.92; 24s £7.74

Legal category: 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 prep: 20 MAR 2025

Calprofen 100mg/5ml Oral Suspension Ibuprofen and Calprofen Ibuprofen Suspension Product Information

Presentation:

Oral suspension containing 100 mg ibuprofen per 5 ml. This product also contains maltitol syrup (E965), sodium methylhydroxybenzoate (E219), sodium propylhydroxybenzoate (E217), propylene glycol (E1520), sodium (1.86 mg/5ml) and ethanol.

Uses:

Treatment of mild to moderate pain, headache, fever, post-immunisation pyrexia, symptoms of colds and flu and minor aches and pains.

Dosage:

For pain and fever in infants 3 to 6 months, weighing over 5 kg: give one 2.5 ml dose up to 3 times in 24 hours; *infants 6 to 12 months*: 2.5 ml three times a day; *children 1 to 2 years*: 2.5 ml three to four times a day; *children 3 to 7 years*: 5 ml three to four times a day; *children 8 to 12 years*: 10 ml three to four times a day.

For relief of post-immunisation fever: give 2.5 ml (50 mg) followed by one further 2.5 ml (50 mg) dose six hours later if necessary. Do not give more than 2 doses in 24 hours and leave 6 to 8 hours between doses.

Contraindications:

Calprofen 100mg/5ml Oral Suspension Ibuprofen and Calprofen Ibuprofen Suspension is contraindicated in patients with hypersensitivity to ibuprofen or to any of the excipients of this product, to aspirin or to other NSAIDs. Patients with an active or history of recurrent peptic ulceration/haemorrhage, perforation or gastrointestinal bleeding, patients with severe heart failure (NYHA Class IV), renal failure, or hepatic failure, and women in the last trimester of pregnancy should not use this product. This medicine should also not be concomitantly used with other NSAIDs or NSAID-containing products. Patients with rare hereditary problems of fructose intolerance should not take this medicine due to the presence of maltitol liquid (E965).

Precautions

This medicine is not recommended for children under 3 months. Undesirable effects NSAID-containing products may be minimised by using the lowest effective dose for the shortest duration necessary to relieve symptoms. This product can mask symptoms of infection, which may lead to delayed initiation of appropriate treatment, thereby worsening the outcome of infection. Monitoring of infection is advised.

Consult a doctor if symptoms persist or worsen. Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease. Renal function may further deteriorate with the use of NSAID-containing products. Renal tubular acidosis and hypokalaemia may occur following acute overdose, intake of ibuprofen-containing products for prolonged periods at high doses (typically greater than 4 weeks), and intake of doses exceeding the recommended daily dose. There is also a risk of renal impairment in dehydrated children. Discussion with a doctor or pharmacist is required prior to initiating treatment in patients with a history of hypertension and/or heart failure, and in patients taking a diuretic. Patients with uncontrolled hypertension, congestive heart failure (NYHA II-III), established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with ibuprofen after careful consideration and high doses (2400 mg/day) should be avoided. Careful consideration should also be exercised before initiating long-term treatment of patients with risk factors for cardiovascular events (e.g., hypertension, hyperlipidaemia, diabetes mellitus, smoking), particularly if high doses are required. Avoid use immediately before or after heart surgery. Cases of Kounis syndrome have also been reported in patients treated with ibuprofen. There is limited evidence that drugs which inhibit cyclooxygenase / prostaglandin synthesis may cause reversible impairment of female fertility. NSAID use may exacerbate preexisting ulcerative colitis and Crohn's disease. Gastrointestinal bleeding, ulceration or perforation has been reported at any time during treatment, with higher risk in increasing NSAID doses, in patients with a history of ulcer complicated by haemorrhage or perforation, and in the elderly. These patients should commence treatment on the lowest dose available. Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding (e.g., oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as aspirin), intake with excessive alcohol, or in patients who are heavy alcohol drinkers. Ibuprofen may cause severe allergic reactions including very rare cases of anaphylaxis. Increased risk of aseptic meningitis has been reported in patients with systemic lupus erythematosus and mixed connective tissue disease. Severe cutaneous adverse reactions (SCARs), including exfoliative dermatitis, erythema multiforme, Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), and acute generalized exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported in association with the use of ibuprofen, usually within the first month of treatment. Maltitol may have a mild laxative effect. Sodium methylhydroxybenzoate (E219) and sodium propylhydroxybenzoate (E217) may cause allergic reactions which could possibly be delayed. This medicine contains 4.67 mg propylene glycol (E1520) per 5 ml dose, or 0.93 mg/ml. This medicine contains 0.0005 mg of alcohol (ethanol) in each 5 ml. The small amount of alcohol in this medicine will not have any noticeable effects. This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'.

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. Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. From the 20th week of pregnancy onward, this medicine use may cause oligohydramnios resulting from foetal renal dysfunction. This may occur shortly after treatment initiation and is usually reversible upon discontinuation. In

addition, there have been reports of ductus arteriosus constriction following treatment in the second trimester, most of which resolved after treatment cessation. During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to cardiopulmonary toxicity and renal dysfunction. Meanwhile at the end of pregnancy, for the mother and the neonate all prostaglandin synthesis inhibitors may prolong bleeding time even at very low doses and inhibit uterine contractions resulting in delayed or prolonged labour. Therefore, during the first and second trimester of pregnancy, this medicine should not be given unless clearly necessary. During the third trimester of pregnancy, this product is contraindicated. Ibuprofen appears in breast milk in very low concentration and is unlikely to affect breast-fed infants adversely.

Side effects:

Uncommon: hypersensitivity reactions with urticaria and pruritus, headache, abdominal pain, dyspepsia, nausea, various skin rashes.

Rare: constipation, diarrhoea, flatulence, gastrointestinal ulcer haemorrhage, vomiting.

Very rare: haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis), severe hypersensitivity reactions, exacerbation of asthma and bronchospasm, aseptic meningitis, exacerbation of colitis and Crohn's disease, gastritis, gastrointestinal haemorrhage, melaena, haematemesis, peptic ulcer, perforation, ulcerative stomatitis, liver disorders, severe cutaneous adverse reactions (SCARs) such as bullous reactions, (including Stevens-Johnson Syndrome, erythema multiforme, exfoliative dermatitis and toxic epidermal necrolysis), acute renal failure, papillary necrosis.

Not known: stroke, Kounis syndrome, myocardial infarction, oedema, hypertension, cardiac failure, acute generalised exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), photosensitivity reactions, hypokalaemia, renal impairment, renal tubular acidosis.

In patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease), single cases of symptoms of aseptic meningitis, such as stiff neck, headache, nausea, vomiting, fever or disorientation have been observed during treatment with ibuprofen.

Please refer to Summary of Product Characteristics for detailed information.

RRP (ex-VAT): 200 ml £6.33; 100 ml £3.83.

Legal category: 200 ml bottle P; 100 ml GSL.

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

PL numbers: 200 ml (P) 15513/0120; 100 ml (GSL) 15513/0147.

Date of prep: 24 JAN 2024

CalCough Infant Syrup (glycerol) Product Information

Presentation:

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

Uses:

Relief of dry tickly coughs.

Dosage:

Children aged 1 to 5 years: two 5 ml spoonfuls (or 10 ml) given three to four times daily. *Children 3 months to 1 year:* one 5 ml 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 (E211) in each 5 ml, which is equivalent to 2 mg/ml, and 18.24 mg propylene glycol (E1520) 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): 125 ml £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

CalCough Children's Syrup (glycerol, sucrose) Product Information

Presentation:

A dark red, blackcurrant flavoured syrup containing glycerol 0.75 ml, sucrose 1.7 g and (excipient with known effect) liquid glucose 2.15 g per 5 ml.

Uses:

For the relief of irritating, tickling dry coughs and sore throats.

Dosage:

Adults, elderly and children over 5 years: 10 ml; *Children 1 to 5 years:* 5 ml. The dose may be repeated three or four times a day.

Contraindications:

In children under 1 year. Hypersensitivity to the active substances or to any of the excipients listed in SPC section 6.1.

Precautions:

Diabetics should take note of the carbohydrate content of this product. Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. This medicine contains 3.53 mg propylene glycol (E1520) in each 5 ml dose, which is equivalent to 0.71 mg/ml. This medicine contains 10 mg sodium benzoate (E211) in each 5 ml which is equivalent to 2 mg/ml. This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'. This medicine contains 0.000053 mg benzyl alcohol in each 5ml which is equivalent to 0.000011 mg/ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may

cause side effects (called “metabolic acidosis”). Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. This is due to an increased risk due to accumulation in young children.

Pregnancy and Lactation:

The safety of this medicine during pregnancy and lactation has not been established but is not considered to constitute a hazard during these periods.

Side effects:

Hypersensitivity reactions, including anaphylaxis.

Please refer to Summary of Product Characteristics for detailed information

RRP (ex-VAT): 125 ml £4.41

Legal category: GSL

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

PL Number: 15513/0392

Date of prep: 24 DEC 2024

CALGEL TEETHING GEL (lidocaine hydrochloride monohydrate, cetylpyridinium chloride) Product Information

Presentation:

Topical gel containing lidocaine hydrochloride monohydrate 0.33% w/w and cetylpyridinium chloride 0.1% w/w.

Uses:

Relief of pain and discomfort associated with teething in children from 5 months, where non-pharmacological treatments have failed to provide sufficient relief.

Dosage:

Children over 5 months: apply a pea-sized amount (0.2 g) of gel onto affected area of gum. The dose can be reapplied after 3 hours if necessary up to a maximum of 6 times in 24 hours. Treatment should be stopped once symptoms have resolved.

Contraindications:

Hypersensitivity to ingredients.

Precautions:

Do not exceed recommended dose. Due to the presence of sucrose and sorbitol in the teething gel, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not use this medicine. Benzyl alcohol in the teething gel may cause allergic reactions. Large amounts of benzyl alcohol can build-up in your body and may cause metabolic acidosis. Benzoic acid may cause local irritation and non-immunologic immediate contact 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. Benzoic acid may also increase jaundice in newborn babies up to 4 weeks old. Do not use for more than a week in young children (less than 3 years old). Castor oil may cause stomach upsets, diarrhoea and skin reactions.

Do not use more than one lidocaine containing product at the same time.

Pregnancy and lactation:

Not applicable.

Side effects:

Not known: hypersensitivity (including dermatitis) or application site reactions

(including Erythema).

RRP (ex-VAT): 10 g £3.41

Legal category: P

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

PL Number: 15513/0015

Date of prep: 11 APR 2023

CALPOL® Blocked Nose Spray (from 3 years) for congestion relief. Non medicine.
Always read the label.