

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.

Long-form EI (for more information, see rule 41 of the PAGB professional code)

Calpol Six Plus Suspension (Paracetamol), 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, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take Six Plus Suspension. Patients with rare hereditary problems of fructose intolerance should not take Six Plus Sugar Free Suspension. 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). Sorbitol and maltitol (Sugar-Free) may have a mild laxative effect. Benzyl alcohol (Sugar-Free) may cause allergic reactions. If patient is pregnant or breastfeeding, or if patient has kidney or liver disease, large amounts of benzyl alcohol (Sugar-Free) 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 Suspension 200ml bottle, £6.91; Six Plus Sugar Free Suspension, 100ml bottle, £4.16, 200ml bottle, £6.91, 12 x 5ml sachets, £4.58; Six Plus Suspension Sugar Free, 80 ml bottle £3.74

Legal category: Six Plus Suspension 200ml bottle: P; 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 Suspension: 15513/0002; 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: 4 January 2021