

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

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 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. 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 £4.16; 24s £6.49

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

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

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