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

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 0.00064mg 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 Number(s): 12s: 15513/0121; 24s: 15513/0082

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