

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 <https://yellowcard.mhra.gov.uk/>

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

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

Presentation:

Suspension containing 100mg Ibuprofen per 5ml. Calprofen 100mg/5ml Suspension also contains maltitol syrup (E965), sodium methylhydroxybenzoate (E219), sodium propylhydroxybenzoate (E217), propylene glycol (E1520), sodium (1.86mg/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: *Infants 3-6 months, weighing over 5kg*: One 2.5 ml dose may be taken 3 times in 24 hours; *Infants 6-12 months*: 2.5ml three times a day; *Children 1-2 years*: 2.5ml three to four times a day; *Children 3-7 years*: 5ml three to four times a day; *Children 8-12 years*: 10ml three to four times a day. Post-immunisation fever: 2.5ml (50mg) followed by one further 2.5ml (50mg) dose six hours later if necessary. No more than 2 doses in 24 hours. Leave 6 – 8 hours between dose.

Contraindications:

Hypersensitivity to ingredients, or to aspirin or other NSAIDs. Peptic ulceration/haemorrhage, perforation or GI bleeding. Concomitant use with NSAIDs. Severe hepatic, renal or heart failure (NYHA Class IV). Women in the last trimester of pregnancy.

Precautions:

The elderly; women trying to conceive; dehydrated children; history of GI toxicity; concomitant medications increasing the risk of GI toxicity; hepatic or renal dysfunction; bronchial asthma or allergic disease; hypertension or heart failure; ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease; long term treatment if risk factors for cardiovascular events exist; SLE; mixed connective tissue disease; use in relation to infections; use immediately before or after heart surgery; excessive alcohol intake; fructose intolerance; long term use at high doses. Cases of Kounis Syndrome and Severe cutaneous adverse reactions (SCARs) such as bullous reactions, (including Stevens-Johnson Syndrome, Erythema multiforme, exfoliative dermatitis and Toxic Epidermal Necrolysis) have been reported. Should be used with caution in patients receiving anticoagulants, antihypertensives and diuretics, corticosteroids, anti-platelet

agents and SSRIs, cardiac glycosides, lithium, methotrexate, ciclosporin, mifepristone, tacrolimus, zidovudine, and quinolone antibiotics. **See SmPC for further details.**

Pregnancy and lactation:

Not recommended.

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 especially in long term use.

Not known: In patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease) during treatment with Ibuprofen, single cases of symptoms of aseptic meningitis, such as stiff neck, headache, nausea, vomiting, fever or disorientation have been observed. Stroke, Kounis syndrome, myocardial infarction, oedema, hypertension and cardiac failure have been reported in association with NSAID treatment, Acute Generalised Exanthematous Pustulosis (AGEP), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS syndrome), photosensitivity reactions, hypokalaemia, renal impairment, renal tubular acidosis

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

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

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

PL numbers: 200ml: bottle 15513/0120. 100ml bottle: 15513/0147.

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