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**Adverse events should also be reported to McNeil Products Limited on 01344 864 042.**

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

### **Presentation:**

Sachets and suspension containing 100mg Ibuprofen per 5ml. Calprofen 100mg/5ml Ibuprofen 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. 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.

### **Pregnancy and lactation:**

Not recommended.

### **Side effects:**

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

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

Very rare: Severe hypersensitivity reactions. Symptoms could be: facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema, or severe shock).

Exacerbation of asthma and bronchospasm, peptic ulcer, perforation or gastrointestinal haemorrhage, melaena, haematemesis. ulcerative stomatitis, gastritis, exacerbation of colitis and Crohn's disease. Acute renal failure, papillary necrosis especially in long term use, associated with increased serum urea and oedema. Liver disorders, haematopoietic disorders, severe forms of skin reactions such as bullous reactions, including Stevens-Johnson Syndrome, erythema multiforme, toxic epidermal necrolysis and aseptic meningitis.

Not known: Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), acute generalised exanthematous pustulosis (AGEP), photosensitivity reactions, renal impairment.

**Price (ex-VAT):** Sachets: 12 x 5ml: £3.45, Bottle 200ml: £5.91; 100ml: £3.58.

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

**PL holder:** McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG. **PL numbers:** Sachets: 15513/0158, 200ml: bottle 15513/0120. 100ml bottle: 15513/0147.

**Date of preparation:** 20 April 2021.

**Prescribing Information for Rx products (ABPI code)**

N/A