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:
Oral suspension containing 100 mg ibuprofen per 5 ml. This product also contains maltitol syrup (E965), sodium methylhydroxybenzoate (E219), sodium propylhydroxybenzoate (E217), propylene glycol (E1520), sodium (1.86 mg/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 in infants 3 to 6 months, weighing over 5 kg: give one 2.5 ml dose up to 3 times in 24 hours; *infants 6 to 12 months:* 2.5 ml three times a day; *children 1 to 2 years:* 2.5 ml three to four times a day; *children 3 to 7 years:* 5 ml three to four times a day; *children 8 to 12 years:* 10 ml three to four times a day.
For relief of post-immunisation fever: give 2.5 ml (50 mg) followed by one further 2.5 ml (50 mg) dose six hours later if necessary. Do not give more than 2 doses in 24 hours and leave 6 to 8 hours between doses.

Contraindications:
Calprofen 100mg/5ml Oral Suspension Ibuprofen and Calprofen Ibuprofen Suspension is contraindicated in patients with hypersensitivity to ibuprofen or to any of the excipients of this product, to aspirin or to other NSAIDs. Patients with an active or history of recurrent peptic ulceration/haemorrhage, perforation or gastrointestinal bleeding, patients with severe heart failure (NYHA Class IV), renal failure, or hepatic failure, and women in the last trimester of pregnancy should not use this product. This medicine should also not be concomitantly used with other NSAIDs or NSAID-containing products. Patients with rare hereditary problems of fructose intolerance should not take this medicine due to the presence of maltitol liquid (E965).

Precautions
This medicine is not recommended for children under 3 months. Undesirable effects NSAID-containing products may be minimised by using the lowest effective dose for the shortest duration necessary to relieve symptoms. This product can mask symptoms of infection, which may lead to delayed initiation of appropriate treatment, thereby worsening the outcome of infection. Monitoring of infection is advised. Consult a doctor if symptoms persist or worsen. Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease. Renal function may further deteriorate with the use of NSAID-containing products. Renal tubular acidosis and hypokalaemia may occur following acute overdose, intake of ibuprofen-containing products for prolonged periods at high doses (typically greater than 4 weeks), and intake of doses exceeding the recommended daily dose. There is also a

risk of renal impairment in dehydrated children. Discussion with a doctor or pharmacist is required prior to initiating treatment in patients with a history of hypertension and/or heart failure, and in patients taking a diuretic. Patients with uncontrolled hypertension, congestive heart failure (NYHA II-III), established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with ibuprofen after careful consideration and high doses (2400 mg/day) should be avoided. Careful consideration should also be exercised before initiating long-term treatment of patients with risk factors for cardiovascular events (e.g., hypertension, hyperlipidaemia, diabetes mellitus, smoking), particularly if high doses are required. Avoid use immediately before or after heart surgery. Cases of Kounis syndrome have also been reported in patients treated with ibuprofen. There is limited evidence that drugs which inhibit cyclooxygenase / prostaglandin synthesis may cause reversible impairment of female fertility. NSAID use may exacerbate preexisting ulcerative colitis and Crohn's disease. Gastrointestinal bleeding, ulceration or perforation has been reported at any time during treatment, with higher risk in increasing NSAID doses, in patients with a history of ulcer complicated by haemorrhage or perforation, and in the elderly. These patients should commence treatment on the lowest dose available. Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding (e.g., oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as aspirin), intake with excessive alcohol, or in patients who are heavy alcohol drinkers. Ibuprofen may cause severe allergic reactions including very rare cases of anaphylaxis. Increased risk of aseptic meningitis has been reported in patients with systemic lupus erythematosus and mixed connective tissue disease. Severe cutaneous adverse reactions (SCARs), including exfoliative dermatitis, erythema multiforme, Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), and acute generalized exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported in association with the use of ibuprofen, usually within the first month of treatment. Maltitol may have a mild laxative effect. Sodium methylhydroxybenzoate (E219) and sodium propylhydroxybenzoate (E217) may cause allergic reactions which could possibly be delayed. This medicine contains 4.67 mg propylene glycol (E1520) per 5 ml dose, or 0.93 mg/ml. This medicine contains 0.0005 mg of alcohol (ethanol) in each 5 ml. The small amount of alcohol in this medicine will not have any noticeable effects. This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'.

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. Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. From the 20th week of pregnancy onward, this medicine use may cause oligohydramnios resulting from foetal renal dysfunction. This may occur shortly after treatment initiation and is usually reversible upon discontinuation. In addition, there have been reports of ductus arteriosus constriction following treatment in the second trimester, most of which resolved after treatment cessation. During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to cardiopulmonary toxicity and renal dysfunction. Meanwhile at the end of pregnancy, for the mother and the neonate all prostaglandin synthesis inhibitors may prolong bleeding time even at very low doses and inhibit uterine contractions resulting in delayed or prolonged labour. Therefore, during the first and second trimester of pregnancy, this medicine should not be given unless clearly necessary. During the third trimester of pregnancy, this product is contraindicated. Ibuprofen appears in breast milk in very low concentration and is

unlikely to affect breast-fed infants adversely.
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.
Not known: stroke, Kounis syndrome, myocardial infarction, oedema, hypertension, cardiac failure, acute generalised exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), photosensitivity reactions, hypokalaemia, renal impairment, renal tubular acidosis.
In patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease), single cases of symptoms of aseptic meningitis, such as stiff neck, headache, nausea, vomiting, fever or disorientation have been observed during treatment with ibuprofen.
Please refer to Summary of Product Characteristics for detailed information.
RRP (ex-VAT): *200 ml* £6.33; *100 ml* £3.83.
Legal category: *200 ml* bottle P; *100 ml* GSL.
PL holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG.
PL numbers: *200 ml (P)* 15513/0120; *100 ml (GSL)* 15513/0147.
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