SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Calprofen Ibuprofen Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 100 mg / 5ml

Excipients with known effect
Also contains maltitol syrup (E965), sodium methylhydroxybenzoate (E219), sodium propylhydroxybenzoate (E217), propylene glycol (E1520), sodium (contains 1.86mg per 5ml) and ethanol.

For the full list of excipients - see section 6.1

3 PHARMACEUTICAL FORM

100 mg / 5ml Oral Suspension
Sugar free, colour free, strawberry flavoured white uniform suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prescription and OTC: Calprofen Ibuprofen Suspension is used as an analgesic for relief of mild to moderate muscular pain, rheumatic pain, post-immunisation pyrexia, symptomatic relief of headache, earache, dental pain, dysmenorrhoea, neuralgia, migraine and backache. It can also be used in minor injuries such as sprains and strains. Ibuprofen 100 mg / 5 ml Ibuprofen Suspension is effective in the relief of feverishness and symptoms of colds and influenza.

In the treatment of non-articular rheumatic conditions, Calprofen Ibuprofen Suspension is indicated for periarticular conditions such as frozen shoulder (capsulitis), bursitis, tendonitis, tenosynovitis and low back pain. Calprofen Ibuprofen Suspension can also be used in soft tissue injuries such as sprains and strains.

4.2 Posology and method of administration

For oral administration and short-term use only.

Children:

For pain and fever - 20mg/kg/day in divided doses (including OTC use).

Infants 3-6 months weighing more than 5 kg:	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 dose of 2.5ml (50mg) six hours later if necessary. No more than 2 doses in 24 hours. If fever is not reduced, consult a doctor.

For Juvenile Rheumatoid Arthritis (prescription only use): Doses up to 30-40mg/kg/day may be taken in three or four divided doses.

Elderly: No special dosage modifications are required unless renal or hepatic function is impaired, in which case dosage should be assessed individually.

Do not give to children under 3 months of age.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms (see section 4.4).

For children aged ≥3 months to ≤5 months: if the child's symptoms worsen or if the symptoms persist for more than 24 hours, consult a doctor.

For children aged 6 months and over: if symptoms worsen or if the symptoms persist for more than 3 days, consult a doctor .

4.3 Contraindications

Hypersensitivity to Ibuprofen or to any of the excipients listed in section 6.1
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Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema or urticaria) in response to aspirin or other non-steroidal anti-inflammatory drugs.

Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).

History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.

Severe heart failure (NYHA Class IV), renal failure or hepatic failure (see section 4.4).
Last trimester of pregnancy (see section 4.6).

4.4. Special warning and precautions for use

Undesirable effects may be minimised by using the lowest effective dose for the shortest possible duration necessary to relieve symptoms (see GI and cardiovascular risks below).

The elderly have an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation, which may be fatal.

Masking of symptoms of underlying infections:
This medicine can mask symptoms of infection, which may lead to delayed initiation of appropriate treatment and thereby worsening the outcome of the infection. This has been observed in bacterial community acquired pneumonia and bacterial complications to varicella. When this medicine is administered for fever or pain relief in relation to infection, monitoring of infection is advised. In nonhospital settings, the patient should consult a doctor if symptoms persist or worsen.

Respiratory:
Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease.

Other NSAIDs:
The use of Ibuprofen with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided (see section 4.5).

SLE and mixed connective tissue disease:
Systemic lupus erythematosus and mixed connective tissue disease – increased risk of aseptic meningitis (see section 4.8).

Renal:
Renal impairment as renal function may further deteriorate (see sections 4.3 and 4.8)
Renal tubular acidosis and hypokalaemia may occur following acute overdose and in patients taking ibuprofen products over long periods at high doses (typically greater than 4 weeks), including doses exceeding the recommended daily dose.

Hepatobiliary disorders:
Hepatic dysfunction (see sections 4.3 and 4.8)

Cardiovascular and cerebrovascular effects:
Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy.

Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤ 1200 mg/day) is associated with an increased risk of arterial thrombotic events.

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 of ibuprofen (2400 mg/day) are required.

Avoid use immediately before or after heart surgery.

Caution should be exercised in patients taking a diuretic.

Cases of Kounis syndrome have been reported in patients treated with ibuprofen. Kounis syndrome has been defined as cardiovascular symptoms secondary to an allergic or hypersensitive reaction associated with constriction of coronary arteries and potentially leading to myocardial infarction.

Impaired female fertility:
There is limited evidence that drugs which inhibit cyclo-oxygenase/prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible upon withdrawal of treatment. The use of ibuprofen is therefore not recommended in women attempting to conceive.

Gastrointestinal:
NSAIDS should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) – as these conditions may be exacerbated (see section 4.8).

GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious GI events.

The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation (see section 4.3), and in the elderly. These patients should commence treatment on the lowest dose available.

Patients with a history of GI toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment.

Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, or anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as aspirin (see section 4.5).

Caution should be taken when using ibuprofen with excessive alcohol or heavy alcohol drinkers. Alcohol may increase the risk of gastrointestinal bleeding.

When GI bleeding or ulceration occurs in patients receiving ibuprofen, the treatment should be withdrawn.

Immune system:
Ibuprofen may cause severe allergic reactions including very rare cases of anaphylaxis (see section 4.8). Symptoms may include hives, facial swelling,

asthma (wheezing), shock, skin reddening, rash or blisters. If any of these symptoms occur, patients should stop use and seek medical help right away.

Severe cutaneous adverse reactions (SCARs):
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 (see section 4.8). Most of these reactions occurred within the first month. If signs and symptoms suggestive of these reactions appear ibuprofen should be withdrawn immediately and an alternative treatment considered (as appropriate).

Dehydration:
There is a risk of renal impairment in dehydrated children.

This product contains maltitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine. Maltitol may have a laxative effect. The calorific value of maltitol is 2.3 kcal/g.

Sodium methylhydroxybenzoate (E219) and sodium propylhydroxybenzoate (E217) may cause allergic reactions which could possibly be delayed.

This medicine contains 4.67mg propylene glycol (E1520) in each 5 ml dose, which is equivalent to 0.93 mg/ml.

This medicine contains 0.0005 mg of alcohol (ethanol) in each 5ml. The amount in 5ml of this medicine is equivalent to less than 1ml beer or wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains less than 1mml sodium (23mg) per 5ml, that is to say essentially ‘sodium-free’.

<u>The label will include:</u>
Read the enclosed leaflet before taking this product.

Do not give this product if your baby or child
- Has (or has had two or more episodes of) a stomach ulcer, perforation or bleeding
- Is allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers
- Is taking other NSAIDs painkillers, or aspirin with a daily dose above 75 mg

Speak to a pharmacist or your doctor before giving this product if your baby or child
- Has or has had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems, or is dehydrated

If you are an adult taking this product you should not take this product in the last 3 months of pregnancy and you should contact your doctor or pharmacist before taking it in the first 6 months of pregnancy, if trying to get pregnant, if you are elderly or if you are a smoker.

Do not give to babies aged from 3 to under 6 months for more than 24 hours.

Do not give to children aged 6 months and older for more than 3 days.

If symptoms persist or worsen, consult your doctor promptly.

Do not exceed the stated dose.

Not recommended for children under 3 months.

4.5 Interaction with other medicinal products and other forms of interaction

Ibuprofen should be avoided in combination with:
Aspirin/Acetylsalicylic acid: Unless low-dose aspirin (not above 75mg daily) has been advised by a doctor, as this may increase the risk of adverse reactions (see section 4.4).

Concomitant administration of ibuprofen and acetylsalicylic acid is not generally recommended because of the potential of increased adverse effects.

Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardioprotective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional ibuprofen use (see section 5.1).

Other NSAIDs including cyclooxygenase-2 selective inhibitors: Avoid concomitant use of two or more NSAIDs as this may increase the risk of adverse effects (see section 4.4).

Ibuprofen should be used with caution in combination with:

Anticoagulants: NSAIDs may enhance the effects of anticoagulants, such as warfarin (see section 4.4).

Antihypertensives and diuretics: NSAIDs may diminish the effect of these drugs. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

Corticosteroids: Increased risk of gastrointestinal ulceration or bleeding (see section 4.4).

Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding (see section 4.4)

Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels.

Lithium: There is evidence for potential increases in plasma levels of lithium.

Methotrexate: There is a potential for an increase in plasma methotrexate.

Ciclosporin: increased risk of nephrotoxicity.

Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effects of mifepristone.

Tacrolimus: possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus.

Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with zidovudine. There is evidence of an increased risk of haemarthroses and haematoma in HIV (+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

Quinolone antibiotics: animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.

4.6 Fertility, pregnancy and lactation

Pregnancy
Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period. 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. Therefore, during the first and second trimester of pregnancy, this medicine should not be given unless clearly necessary. If this medicine is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.
Antenatal monitoring for oligohydramnios and ductus arteriosus constriction should be considered after exposure to this medicine for several days from gestational week 20 onward. This medicine should be discontinued if oligohydramnios or ductus arteriosus constriction are found.
During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:

- cardiopulmonary toxicity (premature constriction/ closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction (see above);

the mother and the neonate, at the end of pregnancy, to:

- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.

- inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, this medicine is contraindicated during the third trimester of pregnancy (see sections 4.3 and 5.3).

Breastfeeding
In limited studies, ibuprofen appears in breast milk in very low concentrations and is unlikely to affect the breastfed infant adversely.

Fertility
See section 4.4 regarding female fertility.

4.7 Effects on ability to drive and use machines

None expected at recommended doses and duration of therapy.

4.8. Undesirable effects

Hypersensitivity reactions have been reported and these may consist of:
a) non-specific allergic reactions and anaphylaxis
b) respiratory tract reactivity, e.g. asthma, aggravated asthma, bronchospasm or dyspnoea
c) various skin reactions, e.g. pruritus, urticaria, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).

The following list of adverse events relates to those experienced with ibuprofen at OTC doses, for short-term use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

The adverse drug reactions (ADRs) observed in patients treated with ibuprofen are listed below by System Organ Class. Frequencies are defined in accordance with current guidance as: Very common (≥1/10); common (≥1/100 to<1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known frequency (cannot be estimated from the available data).

ADRs are presented by frequency category based on 1) incidence in adequately designed clinical trials or epidemiology studies, when available, or 2) when incidence is unavailable, frequency category is listed as 'Not Known'.

System Organ Class	*Incidence*	*Adverse Drug Reaction*
Blood & lymphatic system disorders	*Very rare*	*Haematopoietic disorders (Anaemia, Leucopenia, Thrombocytopenia, Pancytopenia, Agranulocytosis). First signs are fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained*

		bleeding and bruising
Immune system disorders	*Uncommon*	*Hypersensitivity reactions with urticaria and pruritus*
	Very rare	*Severe hypersensitivity reactions: Symptoms could be facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema, or severe shock)*
	Very rare	*Exacerbation of asthma and Bronchospasm*
	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 (see section 4.4)*
Nervous system disorders	*Uncommon*	*Headache*
	Very rare	*Aseptic meningitis – single cases have been reported very rarely*
	Not known	*Stroke**
Cardic disorders	*Not known*	*Kounis syndrome*
	Not known	*Myocardial infarction**
	Not known	*Oedema, Hypertension and Cardiac failure have been reported in association with NSAID treatment*
Gastrointestinal disorders	*Uncommon*	*Abdominal pain*
	Uncommon	*Dyspepsia*
	Uncommon	*Nausea*
	Rare	*Constipation*
	Rare	*Diarrhoea*
	Rare	*Flatulence*
	Rare	*Gastrointestinal ulcer haemorrhage*
	Rare	*Vomiting*
	Very rare	*Exacerbation of Colitis and Crohn's disease (see section 4.4)*
	Very rare	*Gastritis*
	Very rare	*Gastrointestinal haemorrhage, Melaena, Haematemesis, sometimes fatal, particularly in the elderly*
	Very rare	*Peptic ulcer*

	Very rare	*Perforation*
	Very rare	*Ulcerative stomatitis*
Hepatobiliary disorders	*Very rare*	*Liver disorders*
Skin and subcutaneous tissue disorders	*Uncommon*	*Various skin rashes*
	Very rare	*Severe cutaneous adverse reactions (SCARs) such as bullous reactions (including Stevens-Johnson Syndrome, Erythema multiforme, exfoliative dermatitis and Toxic Epidermal Necrolysis)*
	Not known	*Acute Generalised Exanthematous Pustulosis (AGEP)*
	Not known	*Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS syndrome)*
	Not known	*Photosensitivity reactions*
Metabolism and Nutrition Disorders	*Not known*	*Hypokalaemia***
Renal and urinary disorders	*Very rare*	*Acute Renal failure*
	Very rare	*Papillary necrosis especially in long term use, associated with increased serum urea and oedema*
	Not known	*Renal impairment*
	Not known	*Renal tubular acidosis***

*Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see section 4.4).
**Renal tubular acidosis and hypokalaemia have been reported in the post-marketing setting typically following prolonged use of the ibuprofen component at higher than recommended doses.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

In children ingestion of more than 400 mg/kg may cause symptoms. In adults the dose response effect is less clear cut. The half-life in overdose is 1.5-3 hours.

Symptoms
Most patients who have ingested clinically important amounts of NSAIDs will develop no more than nausea, vomiting, epigastric pain, abdominal pain or more rarely diarrhoea. Tinnitus, headache and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as lethargy and drowsiness, occasionally excitation and disorientation or coma. Occasionally patients develop convulsions.

In serious poisoning metabolic acidosis may occur and the prothrombin time/ INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur.

Exacerbation of asthma is possible in asthmatics. Rhabdomyolysis, hypothermia and apnoea (primarily in children) may also rarely occur. Cardiovascular toxicity, including hypotension, cardiac arrhythmias, including ST-segment and T-wave changes, have been reported; ventricular tachycardia/ventricular fibrillation cardiac arrest, and prolonged QTc occurred in fatal cases.

Prolonged use at higher than recommended doses may result in severe hypokalaemia and renal tubular acidosis. Symptoms may include reduced level of consciousness and generalised weakness (see section 4.4 and section 4.8).

Management
Management should be symptomatic and supportive and include the maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal if the patient presents within 1 hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids; propionic acid derivative
ATC Code: M01AE01

Ibuprofen is a propionic acid derivative NSAID that has demonstrated its efficacy by inhibition of prostaglandin synthesis. In humans ibuprofen reduces inflammatory pain, swellings and fever. Furthermore, ibuprofen reversibly inhibits platelet aggregation.

Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. Some pharmacodynamic studies show that when single doses of ibuprofen 400 mg were taken within 8 h before or within 30 min after immediate release acetylsalicylic acid dosing (81 mg), a decreased effect of acetylsalicylic acid on the formation of thromboxane or platelet aggregation occurred. Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardioprotective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional ibuprofen use (see section 4.5).

5.2 Pharmacokinetic properties

Ibuprofen is rapidly absorbed following administration and rapidly distributed throughout the whole body. The excretion is rapid and complete via the kidneys.

It is metabolised to two inactive metabolites and these are rapidly excreted in urine. About 1 percent is excreted in urine as unchanged Ibuprofen and about 14 percent as conjugated Ibuprofen.

Ibuprofen is extensively bound to plasma proteins.

Maximum plasma concentrations are reached 45 minutes after ingestion if taken on an empty stomach. When taken with food, peak levels are observed after 1 to 2 hours. These times may vary with different dosage forms.

The half-life of ibuprofen is about 2 hours.

In limited studies, ibuprofen appears in the breast milk in very low concentrations.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol (E422)
xanthan gum
maltitol syrup (Lycasin 80/55 (E965))
polysorbate 80
saccharin sodium (E954)
citric acid monohydrate
sodium methylhydroxybenzoate (E219)
sodium propylhydroxybenzoate (E217)
purified water and
strawberry flavour (containing propylene glycol (E1520) and ethanol).

6.2 Incompatibilities

None stated except as in ‘Interactions with other medicaments’.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25ºC.
Keep out of the sight and reach of children

6.5 Nature and contents of container

An amber glass bottle sealed with child resistant, tamper evident cap. A syringe with a 2.5 ml and 5 ml measure is supplied with this pack.
Pack sizes available: 200ml
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Shake well before use. Return any leftover medicine to the Pharmacist.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0120

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/07/2009

10 DATE OF REVISION OF THE TEXT

13/03/2026