Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nurofen for Children Cold & Flu & Pain Orange 100mg/5ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 100 mg/5 ml (equivalent to 2.0% w/v)

Excipients with known effects:
Maltitol liquid 2226 mg per 5 ml
Sodium 9.08 mg (0.39 mmol) per 5 ml
Wheat starch 11 mg, containing no more than 0.225 µg gluten per 5 ml

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Suspension

An off-white orange flavoured syrupy suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Reduction of fever and relief of mild to moderate pain, such as cold and flu symptoms, teething pain, headache, sprains and strains and to ease the pain of sore throats and earache.

4.2 Posology and method of administration

Posology:
For short term use only.

The maximum daily dosage of Nurofen for Children Cold & Flu & Pain is 30mg of ibuprofen/kg bodyweight administered in divided doses. The symptomatic treatment of mild to moderate pain, and/or fever in children and adolescents depends on body weight and age respectively – in general with 7 to 10mg/kg body weight as single dosage.

This can be achieved as follows:

Age	Body weight (kg)	Recommended Dosage
3 to 6 months	**5-7.6**	**2.5ml, 3 times a day**
6 to 12 months	**7.7-9**	**2.5ml, 3 times a day**
1 to 3 years	**10-16**	**5 ml, 3 times a day**
4 to 6 years	**17-20**	**7.5 ml, 3 times a day**
7 to 9 years	**21-30**	**10 ml, (two 5ml spoonfuls) 3 times a day**
10 to 12 years	**31-40**	**15 ml, (three 5ml spoonfuls) 3 times a day**

This product should only be given to infants aged 3-6 months who weigh more than 5kg. For infants aged 3-5 months medical advice should be sought if symptoms worsen or not later than 24 hours if symptoms persist. If in children aged from 6 months and in adolescents, this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted. Do not dose more frequently than at 6 hourly intervals. The recommended dose should not be exceeded.
The lowest effective dose should be used for the shortest duration necessary to relieve symptoms (see section 4.4).
Not suitable for children under 3 months of age unless advised by your doctor.

Method of administration:
For oral administration.
For patients with sensitive stomachs the product can be taken during a meal.

4.3 Contraindications

Patients with severe hepatic failure, severe renal failure or severe heart failure (see section 4.4).

History of gastrointestinal bleeding or perforation related to previous NSAIDs therapy. Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding or other gastrointestinal disorders).

Hypersensitivity to ibuprofen or any of the excipients listed in section 6.1.

Patients with a history of hypersensitivity reactions (e.g. bronchospasm, asthma, rhinitis, angioedema or urticaria), associated with acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs (NSAIDs).

During the last trimester of pregnancy (see section 4.6)

4.4 Special warnings and precautions for use

The use of Nurofen for Children Cold & Flu & Pain Orange 100mg/5ml Oral Suspension with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided (see section 4.5).

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to relieve symptoms.

Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal (see section 4.2). Prolonged use of NSAIDs in the elderly is not recommended. Where prolonged therapy is required, patients should be reviewed regularly.

Gastrointestinal bleeding, ulceration and perforation: GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without any 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. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low dose aspirin, or other drugs likely to increase gastrointestinal risk (see below and 4.5).

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, anticoagulants such as warfarin, selective serotonin reuptake inhibitors or anti-platelet agents such as aspirin (see section 4.5).

When GI bleeding or ulceration occurs in patients receiving Nurofen for Children Cold & Flu & Pain Orange100mg/5ml Oral Suspension, the treatment should be withdrawn.

NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's Disease) as their condition may be exacerbated (see section 4.8).

Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patients with cardiac impairment (see section 4.5), a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with NSAID therapy.

Cardiovascular and cerebrovascular effects: Clinical trial and epidemiological data suggest that use of ibuprofen, particularly at high doses (2400mg daily) and in long term treatment 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. ≤ 1200mg daily) is associated with an increased risk of myocardial infarction.

Cases of Kounis syndrome have been reported in patients treated with Nurofen for Children. 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.

Caution is required in patients with renal impairment (see section 4.3) since renal function may deteriorate. In patients with renal impairment, renal function should be monitored as it may deteriorate following the use of NSAIDs.

Caution is required in patients with hepatic impairment (see section 4.3 and 4.4)

As NSAIDs can interfere with platelet function, they should be used with caution in patients with idiopathic thrombocytopenic purpura (ITP), intracranial haemorrhage and bleeding diathesis.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Severe cutaneous adverse reactions (SCARs): Severe cutaneous adverse reactions (SCARs) including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised 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 of treatment. If signs and symptoms suggestive of these reactions appear, ibuprofen should be withdrawn immediately and an alternative treatment considered (as appropriate).

Masking of symptoms of underlying infections:
Nurofen for Children 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 Nurofen for Children is administered for fever or pain relief in relation to infection, monitoring of infection is advised. In non-hospital settings, the patient should consult a doctor if symptoms persist or worsen.

Exceptionally, varicella can be at the origin of serious cutaneous and soft tissue infectious complications. It is advisable to avoid use of Nurofen for Children Cold & Flu & Pain in case of varicella.

There is some evidence that drugs which inhibit cyclo-oxygenase/prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible on withdrawal of treatment.

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

Caution is advised in patients with systemic lupus erythematosus as well as those with connective tissue disease (see section 4.8)

This product contains maltitol liquid. Patients with rare hereditary problems of fructose intolerance should not take this medicine.
This medicinal product contains 9.08 mg sodium per 5 ml, equivalent to 0.45% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This medicinal product contains wheat starch. Wheat starch may contain gluten, but only in trace amounts, and is therefore considered safe for people with coeliac disease.

There is a risk of renal impairment in dehydrated children and adolescents.

4.5 Interaction with other medicinal products and other forms of interaction

Ibuprofen should be avoided in combination with:

Acetylsalicylic Acid (Aspirin): unless low dose acetylsalicylic acid (Aspirin) (not above 75mg daily) has been advised by a doctor, as this may increase the risk of adverse reactions (see section 4.4). Experimental data suggest that ibuprofen may inhibit the effect of low dose acetylsalicylic acid (aspirin) on platelets aggregation when they are dosed concomitantly.

However, the limitations of these data and the uncertainties regarding the extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional 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).

It is considered unsafe to take NSAIDs in combination with warfarin or heparin unless under direct medical supervision.

Care should be taken in patients treated with any of the following drugs as interactions have been reported:

Anti-hypertensives (ACE inhibitors and Angiotensin II Antagonists) and diuretics: NSAIDs may reduce the effect of diuretics and other antihypertensive drugs. In some patients with compromised renal function (e.g. dehydrated patients or elderly patients with compromised renal function) the co-administration of an ace inhibitor or Angiotensin II antagonist and agents that inhibit cyclo-oxygenase may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible. These interactions should be considered in patients taking ibuprofen concomitantly with ACE inhibitors or angiotensin II antagonists. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy and periodically thereafter. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

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

Anti-coagulants: NSAIDs may enhance the effects of anticoagulants, such as warfarin (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 cardiac glycoside levels.

Lithium: decreased elimination of lithium.

Methotrexate: decreased elimination of methotrexate.

Cyclosporin: increased risk of nephrotoxicity with NSAIDs.

Other NSAIDs: avoid concomitant use of two or more NSAIDs.

Aminoglycosides: reduction in renal function in susceptible individuals, decreased elimination of aminoglycoside and increased plasma concentrations.

Probenecid: reduction in metabolism and elimination of NSAID and metabolites.

Oral hypoglycemic agents: inhibition of metabolism of sulfonylurea drugs, prolonged half-life and increased risk of hypoglycaemia.

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

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

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, ibuprofen 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, ibuprofen should not be given unless clearly necessary. If ibuprofen 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 ibuprofen for several days from gestational week 20 onward. Ibuprofen 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, ibuprofen is contraindicated during the third trimester of pregnancy (section 4.3 and 5.3).

Breastfeeding:
Ibuprofen and its metabolites can pass in very small concentrations (0.0008% of the maternal dose) into the breast milk. No harmful effects to infants are known, so it is not necessary to interrupt breast-feeding for short-term treatment with the recommended dose for mild to moderate pain and fever.

Fertility:
See section 4.4 on Special Warnings and Precautions for use regarding female fertility

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

The list of the following adverse effects relates to those experienced with ibuprofen at OTC doses (maximum 1200mg ibuprofen per day), for short-term use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

Adverse events which have been associated with ibuprofen are given below, tabulated by system organ class and frequency.

The frequencies are defined as follows
Very common, (≥1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1000 to <1/100, Rare (≥1/10000 to <1/1000), Very Rare (<1/10000), Not known (cannot be estimated from the available data)

System Organ Class	Frequency	Adverse Events
Gastrointestinal Disorders	Uncommon	Abdominal pain, dyspepsia and nausea [5]
	Rare	Diarrhoea, flatulence, constipation and vomiting
	Very rare	Peptic ulcer, gastrointestinal perforation or gastrointestinal haemorrhage, melaena and haematemesis. [6] Exacerbation of colitis and Crohn's disease [7] Mouth ulceration and gastritis.

Nervous System Disorders	Uncommon	Headache
	Very rare	Aseptic meningitis [3]
Renal and Urinary Disorders	Very rare	Acute renal failure [9]
Hepatobiliary Disorders	Very rare	Liver disorder [8] Cholestatic jaundice, hepatitis, elevation of serum enzymes.
Blood and Lymphatic system Disorders	Very rare	Haematopoietic disorders [1]
Skin and Subcutaneous Tissue Disorders	Very rare	Severe cutaneous adverse reactions (SCARs) (including erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis) [2]
	Uncommon:	Skin rash [2]
	Not known	Drug reaction with eosinophilia and systemic symptoms (DRESS). Acute generalised exanthematous pustulosis (AGEP). Photosensitivity reactions
Immune System Disorders	Uncommon	Hypersensitivity reactions with urticaria and pruritus [2]
	Very rare	Severe hypersensitivity reactions, including facial, tongue and throat swelling, dyspnoea, tachycardia and hypotension (anaphylaxis, angioedema or severe shock) [2]
Hypersensitivity Disorders	Very rare	Severe hypersensitivity reactions. Symptoms could be: facial, tongue and larynx swelling, dyspnoea, tachycardia, hypotension, (anaphylaxis, angioedema or severe shock). Exacerbation of asthma and bronchospasm.
Cardiac Disorders	Very rare	Cardiac failure and oedema [4]
	Not known	Kounis syndrome
Vascular Disorders	Very rare	Hypertension [4]
Respiratory, Thoracic and Mediastinal Disorders	Very rare	Respiratory tract reactivity compromising asthma, aggravated asthma, bronchospasm or dyspnoea [2]
Investigations	Very rare	Haemoglobin decreased, urea renal clearance decreased
Infections and infestations	Very rare	Exacerbation of infections related inflammation (e.g. development of necrotizing fasciitis), in exceptional cases, severe skin infections and soft-tissue complications may occur during a varicella infection.

Description of Selected Adverse Reactions

[1] Examples include anaemia, leucopenia, thrombocytopenia, pancytopenia and agranulocytosis. First signs are fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.

[2]Hypersensitivty reactions: These may consist of (a) non-specific allergic reactions and anaphylaxis, (b) respiratory tract reactivity, including asthma, aggravated asthma, bronchospasm, and dyspnoea, or (c) various skin reactions, including pruritus, urticaria, purpura, angioedema and, more rarely, exfoliative and bullous dermatoses, including toxic epidermal necrolysis, Stevens-Johnson Syndrome and erythema multiforme.

[3]The pathogenic mechanism of drug-induced aseptic meningitis is not fully understood. However, the available data on NSAID-related aseptic meningitis points to a hypersensitivity reaction (due to a temporal relationship with drug intake, and disappearance of symptoms after drug discontinuation). Of note, 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.

[4]Clinical trial epidemiological data suggest that use of ibuprofen (particularly at high doses 2400mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (e.g. myocardial infarction or stroke), (see section 4.4).

[5]The adverse events observed most often are gastrointestinal in nature.

[6]Sometimes fatal, particularly in the elderly (see section 4.4).

[7]See section 4.4.

[8]Especially in long term treatment

[9]Decrease of urea excretion and oedema can occur. Papillary necrosis, especially in long-term use, and increased serum urea concentrations have been reported.

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 HPRA Pharmacovigilance. Website: www.hpra.ie.

4.9 Overdose

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

a) Symptoms of Overdosing

Most patients who have ingested clinically important amounts of NSAIDs will develop no more than nausea, vomiting, abdominal pain, or more rarely diarrhoea.
Tinnitus, headache, nystagmus, blurred vision, hypotension and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as dizziness, drowsiness, loss of consciousness, occasional 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. Prolonged use at higher than recommended doses or overdose may result in renal tubular acidosis and hypokalaemia.

b) Therapeutic Measure in Overdosing

Patients should be treated symptomatically as required. Use supportive care where appropriate. Management should 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 one 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. No specific antidote is available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Anti-inflammatory and anti-rheumatic products, non-steroids, propionic acid derivative.
ATC Code: M01AE01

Ibuprofen is an NSAID that has demonstrated its efficacy in the common animal experimental inflammation models by inhibition of prostaglandin synthesis. In humans, ibuprofen reduces inflammatory pain, swelling and fever.Furthermore, ibuprofen reversibly inhibits platelet aggregation.

The clinical efficacy of ibuprofen has been demonstrated in fever and in pain associated with headache, toothache and dysmenorrhoea. Furthermore it has been demonstrated in patients with pain and fever associated with cold and flu and in pain models such as sore throat, muscular pain, soft tissue injury, backache.

Clinical data have shown that ibuprofen in oral suspension has an onset of antipyretic action after 15 minutes. Single ibuprofen doses in the range of 6 to 10 mg/kg body weight can provide up to 8 hours antipyretic and analgesic effect.

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelets aggregation when they are dosed concomitantly. In one study, when a single dose of ibuprofen 400mg was taken within 8 h before or within 30 min after immediate release aspirin (81mg), a decreased effect of ASA on the formation of thromboxane or platelet aggregation occurred. However, the limitations of these data and the uncertainties regarding extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect isconsidered to be likely for occasional ibuprofen use.

5.2 Pharmacokinetic properties

Ibuprofen is rapidly absorbed from the gastrointestinal tract and is rapidly distributed throughout the body. Peak serum concentrations occur about 45 minutes after administration of Nurofen for Children 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 elimination half life is approximately 2 hours. Ibuprofen is metabolised in the liver to two major inactive metabolites and these together with unchanged ibuprofen are excreted by the kidney either as such or as conjugates. Excretion by the kidney is both rapid and complete.

Ibuprofen is extensively bound to plasma proteins.

No special pharmacokinetic studies have been carried out in children. However, pharmacokinetic parameters of ibuprofen in children are comparable with those in adults.

5.3 Preclinical safety data

The toxicity of ibuprofen in animal experiments was observed as lesions and ulcerations in the gastrointestinal tract.
Ibuprofen did not show a mutagenic potential in vitro and was not carcinogenic in rats and mice.
Experimental studies have demonstrated that ibuprofen crosses the placenta, but there is no evidence of any teratogenic action.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maltitol syrup
Citric acid
Sodium Citrate
Sodium chloride
Sodium saccharin
Domiphen bromide
Polysorbate 80
Xanthan gum
Orange Flavour M16014 Quest
Glycerine
Wheat starch
Purified Water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

No special storage requirements.

6.5 Nature and contents of container

Amber-coloured polyethylene terephthalate (PET) bottle with a child-resistant polypropylene or polyethylene closure fitted with a low density polyethylene liner. The bottle contains 50 ml, 100 ml, 150 ml or 200ml of product.

Amber-coloured 30ml glass bottle with a child-resistant polypropylene closure fitted with a low density polyethylene liner.

The product is supplied with one of the following dosing devices:

- A double-ended spoon, with a 2.5 ml bowl at one end and a 5 ml bowl at the other end

OR

- A 5ml dosing syringe, comprising of an orange PE piston and a clear PP barrel

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Shake the bottle before use.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd,
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0979/066/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th October 2014

10 DATE OF REVISION OF THE TEXT

January 2025