Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nurofen Express Maximum Strength 400 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Ibuprofen 400mg (as sodium dihydrate)

Excipients with known effect:

Sodium: 55.89mg (2.43 mmol) per tablet.

Sucrose: 186.2mg per tablet.

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Coated Tablet.
A white to off-white, biconvex, round, sugar coated tablet with an identifying logo in red on one face.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As an anti-inflammatory, analgesic and antipyretic for short-term management of mild to moderate pain such as is associated with headache, dental pain, fever, period pain, muscular strain, backache, and for the management of the symptoms of head colds and influenza.

4.2 Posology and method of administration

For oral administration and short term use only.

Adults and children over 12 years: Initial dose is one tablet and subsequently if necessary, one every four hours with a maximum of 3 tablets in a 24 hour period i.e. a maximum dose of 1200mg in a 24 hour period.

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

If the medicinal product is required for more than 3 days or if the symptoms worsen, the patient should consult a doctor.

If in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

Not suitable for children under 12 years of age without medical advice

NSAIDs should be used with particular caution in elderly patients who are more prone to adverse events. The lowest dose compatible with adequate safe clinical control should be employed please refer to section 4.4. Treatment should be reviewed at regular intervals and discontinued if no benefit is seen or intolerance occurs.

4.3 Contraindications

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 disorder.

Patients with a known history of hypersensitivity reactions (e.g. asthma, bronchospasm, rhinitis, angioedema or urticaria) in response to ibuprofen (the active substance) or any of the excipients in Nurofen Express, acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs (NSAIDs).

Use in children under 12 years of age.
Patients with severe hepatic failure or severe renal failure (See Section 4.4).

Severe heart failure (NYHA Class IV).

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

During the last trimester of pregnancy (See Section 4.6).

4.4 Special warnings and precautions for use

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.

Other NSAIDs: Use 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, due to increased risk of aseptic meningitis (see section 4.8).

Gastrointestinal bleeding, ulceration and perforation: 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 – Undesirable effects).

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.

When GI bleeding or ulceration occurs in patients receiving Nurofen Express Maximum Strength 400mg Tablets, the treatment should be withdrawn.

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).

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.

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

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 syndrome) 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. 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 Express Maximum Strength 400 mg Tablets 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 Express Maximum Strength 400 mg Tablets are administered for fever or pain relieve 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 ibuprofen in cases of varicella.

Renal: Renal impairment as renal function may deteriorate (see section 4.3 and 4.8).

Hepatic: Hepatic dysfunction (see section 4.3 and 4.8).

Respiratory: Patients with bronchospasm or SLE should consult their doctor before taking this medicine. Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease.

Impaired female fertility: 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.

Other Warnings: As NSAIDs can interfere with platelet function, they should be used with caution in patients with intracranial haemorrhage and bleeding diathesis.

If you are pregnant, elderly or have asthma or are receiving regular medical treatment please consult your doctor before taking this medication.

Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained and treatment should be discontinued. The diagnosis of 'Medication Overuse Headache should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.

Advice for patients on a controlled sodium diet: This medicinal product contains 55.89mg sodium per tablet, equivalent to 2.79% of the WHO recommended maximum daily intake of 2g of sodium for an adult. This should be considered in patients whose overall intake of sodium must be markedly restricted.

Sucrose: Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

There is a risk of renal impairment in dehydrated adolescents.

4.5 Interaction with other medicinal products and other forms of interaction

Ibuprofen should be avoided in combination with:

Acetylsalicylic acid: 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:

- **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). It is considered unsafe to take NSAIDs in combination with warfarin or heparin unless under direct medical supervision.
- **Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs):** increased risk of gastrointestinal bleeding (see section 4.4).
- **Antihypertensives (ACE inhibitors and Angiotensin II Antagonists) and Diuretics:** NSAIDs may diminish the effects of these 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 agents that inhibit cyclooxygenase may result in further deterioration of renal function, including possible acute renal failure. These interactions should be considered in patients taking a coxib 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.
- **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.
- **Ciclosporin:** 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 hypoglycaemic agents**: inhibition of metabolism of sulfonylurea drugs, prolonged half-life and increased hypoglycaemia.
- **Zidovudine:** There is evidence of an increased risk of haemarthroses and haematoma in HIV (+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.
- **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.
- **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 construction 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. Anti-natal monitoring for oligohydramnios and ductus arteriosus constriction should be considered after exposure for several days from gestational week 20 onward. Treatment 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 (with premature constriction/closure of the ductus arteriosus and pulmonary hypertension);
- Renal dysfunction(see above).The mother and the neonate, at the end of the 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 (see section 4.3).

Lactation/Breastfeeding:
In limited studies, ibuprofen and its metabolites appears in the breast milk in very low concentration (0.0008% of the maternal dose) and is unlikely to affect the breast-fed infant adversely.

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

The list of the following adverse effects relates to those experienced with ibuprofen at OTC doses (maximum 1200mg 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, listed by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and ‹1/10), uncommon (≥1/1000 and ‹1/100), rare (≥1/10,000 and ‹1/1000), very rare (‹1/10,000) and not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

The adverse events observed most often are gastrointestinal in nature. Adverse events are mostly dose-dependent, in particular the risk of occurrence of gastrointestinal bleeding which is dependent on the dosage range and duration of treatment.

The undesirable effects are less frequent when the maximum daily dose is 1200mg.

Clinical studies suggest that the 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).

System Organ Class	Frequency	Adverse Event
Blood and 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, nose and skin bleeding, and bruising.
Immune System disorders	**Uncommon**	Hypersensitivity reactions consisting of 1: Urticaria and pruritus
	Very rare:	Severe hypersensitivity reactions. Symptoms could be facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema or severe shock). Aggravated asthma, bronchospasm
	Not Known	Respiratory tract reactivity comprising asthma or dyspnoea.
Nervous System disorders	**Uncommon:**	Headache, dizziness.
	Very rare	Aseptic meningitis 2
Ear and labyrinth disorders	**Uncommon:**	Hearing impaired
Cardiac disorders	**Very rare:**	Cardiac failure and oedema
	Not known:	Kounis syndrome
Vascular disorders	**Very rare:**	Hypertension
Gastrointestinal disorders	**Uncommon:**	Abdominal pain, dyspepsia and nausea.
	Rare:	Diarrhoea, flatulence, constipation and vomiting.
	Very rare:	Peptic ulcers, perforation or gastrointestinal haemorrhage, melaena, haematemesis, sometimes fatal, particularly in the elderly (see Section 4.4). Ulcerative stomatitis, gastritis. Exacerbation of colitis and Crohn's disease (see Section 4.4).
Hepatobiliary disorders	**Very rare:**	Liver disorders, especially in long-term treatment.
Skin and Subcutaneous Tissue disorders	**Uncommon**	Various skin rashes
	Very rare:	Severe cutaneous adverse reactions (SCARs) (including erythema multiforme, exfoliative dermatitis, Stevens-Johnson Syndrome and toxic epidermal necrolysis)
	Not known	Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome). Acute generalised exanthematous pustulosis (AGEP) Photosensitivity reactions
Renal and Urinary disorders	**Very rare:**	Acute renal failure, papillary necrosis, especially in long-term use associated with increased serum urea and oedema
Investigations	**Very rare:**	Decreased haemoglobin levels and 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 Hypersensitivity reactions have been reported following treatment with ibuprofen. These may consist of (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract activity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders including rashes of various types, pruritus, urticaria, purpura, angioedema and more rarely, exfoliative and bullous dermatoses (including toxic epidermal necrolysis, Stevens-Johnson Syndrome and erythema multiforme).

2 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, single cases of symptoms of aseptic meningitis (such as stiff neck, headache, nausea, vomiting, fever or disorientation) have been observed during treatment with ibuprofen in patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease).

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 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, or more rarely diarrhoea. Tinnitus, headache, dizziness, nystagmus, blurred vision, loss of consciousness and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as vertigo, drowsiness, occasionally excitation and disorientation or coma. Occasionally patients develop convulsions. In serious poisoning hyperkalaemia and 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, liver damage, hypotension, respiratory depression and cyanosis 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.

Management: No specific actions antidote is available. 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 or gastric emptying if the patient presents within one hour of ingestion of a potentially toxic amount. If ibuprofen has already been absorbed, alkaline substances may be administered to promote the excretion of acid ibuprofen in the urine. 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: propionic acid derivative
ATC Code: M01A E01

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, swellings and fever. Furthermore, ibuprofen reversibly inhibits platelet aggregation.

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

A study in dental pain has shown that patients experienced statistically significant pain relief in 15 minutes after the administration of 2 x Nurofen 256 mg Tablets, compared with placebo. In this study, significantly more patients achieved

meaningful pain relief after administration of 2 x Nurofen 256 mg Tablets than after administration of paracetamol tablets (96.3% vs 67.9%). These patients also achieved significantly greater reduction in pain intensity and greater pain relief over 6 hours compared with patients receiving paracetamol. Using measures of distractibility, patients receiving sodium ibuprofen experienced significantly greater benefit than those receiving placebo.

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 (81mg), 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 from the gastrointestinal tract. Ibuprofen is extensively bound to plasma proteins. Ibuprofen diffuses into the synovial fluid.

Peak plasma concentration of ibuprofen occurs 1 - 2 hours after administration of ibuprofen acid. The median peak plasma concentration after administration of Nurofen Express tablets containing 512 mg of sodium ibuprofen is achieved in approximately 35 minutes.

Ibuprofen is metabolised in the liver to two major metabolites with primary excretion via the kidneys, either as such or as major conjugates, together with a negligible amount of unchanged ibuprofen. Excretion by the kidney is both rapid and complete.

Elimination half-life is approximately 2 hours.

No significant differences in pharmacokinetic profile are observed in the elderly.

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

Product specific pharmacokinetic properties:

A comparison of 2 x Nurofen Express Tablets (sodium ibuprofen 256mg) with 2 x Nurofen tablets (ibuprofen acid 200mg) showed that the median peak plasma concentration was achieved more than twice as fast for the sodium ibuprofen (35 min) compared to the standard Nurofen tablets (90 min).

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

Croscarmellose sodium (E468)
Xylitol (E967)
Microcrystalline cellulose (E460)
Magnesium stearate (E572)
Colloidal anhydrous silica (E551)
Carmellose sodium (E466)
Talc (E553b)
Acacia spray dried (E414)
Sucrose
Titanium dioxide (E171)
Macrogol 6000 powder
Red print ink*

*(containing: Shellac (E904), iron oxide red (E172), N-butyl alcohol, isopropyl alcohol, propylene glycol (E1520), ammonium hydroxide (E257) and simethicone)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

A push through laminate blister tray consisting of opaque, white 250 micron PVC with 90gsm polyvinylidene chloride (PVdC), heat-sealed to 20 micron aluminium foil. The blisters are packed into cardboard cartons.

Each pack may contain 4, 6, 10, 12, 14, 18, 20, 22, 24 tablets.

Not all pack sizes or types may be marketed.

6.6 Special precautions for disposal and other handling

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA0979/032/011

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th May 2011

Date of last renewal: 10th August 2016

10 DATE OF REVISION OF THE TEXT

March 2025