Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nurofen Rapid Relief Maximum Strength 400mg Liquid Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each liquid capsule contains 400mg ibuprofen.
Excipients with known effect:
Sorbitol 67.24 mg per capsule
Ponceau 4R (E124), 1.25 mg per capsule
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule soft

An oval shaped clear capsule with a translucent red gelatin shell, containing a clear liquid, printed with 'NUROFEN' in white.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As an anti-inflammatory, analgesic and antipyretic for short term management of mild to moderate pain, fever and inflammation such as is associated with headache, dental pain, period pain, muscular strain, neuralgia, rheumatic pain and migraine 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. Do not chew.
The lowest effective dose should be used for the shortest duration necessary to relieve symptoms (see section 4.4).

The patient should consult a doctor if symptoms persist or worsen, or if the product is required for more than 3 days.
Adults, the elderly and children over 12 years: 400mg taken with water up to three times a day as required. Leave at least four hours between doses with a maximum of 1200mg in any 24 hour period. If in adolescents this medicinal product is required for more than 3 days or if symptoms worsen a doctor should be consulted.
Not for use by children under 12 years of age.
Elderly: 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 (See Section 4.4).

Treatment should be reviewed at regular intervals and discontinued if no benefit is seen or intolerance occurs.

4.3 Contraindications

Known hypersensitivity to the active substance, ibuprofen, or to any of the constituents, acetylsalicylic acid (Aspirin), or other NSAIDs.
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).

Patients who have previously shown hypersensitivity (e.g. bronchospasm, asthma, rhinitis, angioedema or urticaria) in response to ibuprofen, 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).

During the third 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. .
If symptoms persist for more than 3 days, patients should be advised to consult their doctor.
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.
Other NSAIDs: The use of this product with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided (see section 4.5).
Respiratory: Bronchospasm may be precipitated in patients suffering from, or with a previous history of, bronchial asthma or allergic disease.
Renal: Caution is required in patients with renal impairment since renal function may deteriorate (see section 4.3 and 4.8). The dose should be as low as possible and renal function should be monitored.

Hepatic: Hepatic impairment (see section 4.8).

Gastrointestinal effects: 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).

Gastrointestinal 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.

When GI bleeding or ulceration occurs in patients receiving Nurofen Rapid Relief Maximum Strength 400mg Liquid Capsules, the treatment should be withdrawn.

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).

Cardiovascular and cerebrovascular effects: Caution 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.

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

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 generalized exanthematous pustulosis (AGEAGEP), 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 Rapid Relief Maximum Strength 400mg Liquid Capsules 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 Rapid Relief Maximum Strength 400mg Liquid Capsules 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 advisable to avoid use of ibuprofen in cases of varicella.

SLE and mixed connective tissue disease: Caution is advised in patients with systemic lupus erythematosus as well as those with connective tissue disease, due to increased risk of aseptic meningitis (see section 4.8).

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

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.

Product specific special warnings:
This medicine contains Ponceau 4R, which may cause allergic reactions.
As each Nurofen Rapid Relief Maximum Strength 400mg Liquid Capsule contains 67.24 mg of sorbitol, patients with rare hereditary problems of fructose intolerance 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 (like other NSAIDs) should be used with caution in combination with 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-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-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.

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

Lithium: decreased elimination of lithium.

Methotrexate: decreased elimination of methotrexate.

Cyclosporin: increased risk of nephrotoxicity with NSAIDs.

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.

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

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

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 of 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 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. Increased formation of oedema in the mother could occur. Consequently, ibuprofen is contraindicated during the third trimester of pregnancy (see section 4.3).

Breast-feeding:
Ibuprofen and its metabolites can pass in very small concentrations (0.0008% of the maternal dose) into the breast milk and is unlikely to affect the breast-fed infant adversely. 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 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 events relates to those experienced with ibuprofen at OTC doses (maximum 1200mg per day), in 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. Frequencies are defined as: 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) and not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

The most commonly observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur (see section 4.4). Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease (see section 4.4) have been reported following administration. Less frequently, gastritis has been observed.

	System Organ Class		**Frequency**		**Adverse Event**	
	Blood and Lymphatic system Disorders		Very rare		Haematopoietic disorders[1]	
	Immune System Disorders		Uncommon		Hypersensitivity reactions consisting of urticaria and pruritus[2]	
			Very rare		Severe hypersensitivity reactions. Symptoms could be facial, tongue and throat swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema or severe shock)[2]	
	Nervous System Disorders		Uncommon		Headache	
			Very rare		Aseptic meningitis[3]	
	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 of asthma, aggravated asthma, bronchospasm or dyspnoea[2]	
	Gastrointestinal Disorders		Uncommon		Abdominal pain, nausea and dyspepsia[5]	
			Rare		Diarrhoea, flatulence, constipation and vomiting	
			Very rare		Peptic ulcers, perforation or gastrointestinal haemorrhage, melaena, haematemesis[6] Mouth ulceration and gastritis	
			Not known		Exacerbation of colitis and Crohn's disease[7]	
	Hepatobiliary Disorders		Very rare		Liver disorders	
	Skin and Subcutaneous Tissue Disorders		Uncommon		Skin rash[2]	
			Very rare		Severe cutaneous adverse reactions (SCARs) (including erythema multiforme, exfoliative dermatitis, Stevens-Johnson Syndrome and toxic epidermal necrolysis)[2]	
			Not known		Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) Acute generalized exanthematous pustulosis (AGEP) Photosensitivity reactions	
	Renal and Urinary Disorders		Very rare		Acute renal failure[8]	
	Investigations		Very rare		Decreased haemoglobin levels, 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 and flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.

[2]Hypersensitivity reactions have been reported. These may consist of (a) non-specific allergic reactions and anaphylaxis (b) respiratory tract activity, e.g. asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) various skin reactions, 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).
[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, 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).
[4]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).
[5]The adverse events observed most often are gastrointestinal in nature.
[6]Sometines fatal, particularly in the elderly
[7]See Section 4.4
[8]Especially in long-term use, associated with increased serum urea and oedema. Also includes papillary necrosis.

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 adults the dose response effect is less clear cut than in children where ingestion of more than 400mg/kg may cause symptoms. 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, abdominal pain or more rarely diarrhoea. Tinnitus, headache, dizziness and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as drowsiness, nystagmus, blurred vision, 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, loss of consciousness, hypotension and liver damage may occur. Exacerbation of asthma is possible in asthmatics. A dose in excess of 200mg/kg carried a risk of causing toxicity.

Prolonged use at higher than recommended doses or overdose may result in renal tubular acidosis and hypokalaemia.

Management: No specific 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 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Anti-inflammatory and anti-rheumatic products non-steroids, propionic acid derivatives.

ATC Code: M01AE01

Ibuprofen is a propionic acid derivative, having analgesic, anti-inflammatory and antipyretic activity.
The drug's therapeutic effects as a non-steroidal anti-inflammatory are thought to result from inhibitory activity on prostaglandin synthetase. 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 400mg 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).

Product specific pharmacodynamic properties
Ibuprofen is dissolved in a hydrophilic solvent inside a gelatin shell. On ingestion the gelatin shell disintegrates in the gastric juice releasing the solubilized ibuprofen for absorption.

5.2 Pharmacokinetic properties

The ibuprofen from Nurofen Rapid Relief Maximum Strength 400mg Liquid Capsules is absorbed to the same extent as ibuprofen from Nurofen tablets, the AUC0-α being equivalent. Ibuprofen is rapidly absorbed from Nurofen Rapid Relief Maximum Strength 400mg Liquid Capsules with maximum plasma concentration achieved in 30 minutes. In comparison, the maximum plasma concentration of Nurofen tablets is achieved in 90 minutes. When taken with food, plasma peak levels may be delayed.

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

Peak plasma concentration of ibuprofen occurs 1-2 hours after administration of ibuprofen acid. When taken with food, peak plasma levels may be delayed. These times may vary with different dosage forms.

Elimination half life is approximately 2 hours.

Following hepatic metabolism (hydroxylation, carboxylation, conjugation), the pharmacologically inactive metabolites are completely eliminated, mainly renally (90%), but also with the bile. The elimination half-life in healthy individuals and those with liver and kidney diseases is 1.8 to 3.5 hours. Plasma-protein binding is about 99%.

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

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents
Macrogol 600
Potassium hydroxide (for pH adjustment)

Capsule shell
Gelatin
Sorbitol liquid, partially dehydrated
Purified water
Ponceau 4R (E124)
Lecithin, isopropyl alcohol, nitrogen and medium chain triglycerides.

Printing ink
Opacode WB white NS-78-18011 (contains the following materials titanium dioxide propylene glycol, isopropyl alcohol and HPMC 2910/Hypromellose 3cP.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

The product is packed in a blister pack consisiting of base material 250 micron white opaque polyvinyl chloride (PVC), coated with 90 gm2 polyvinylidine chloride (PVDC 90) and sealed to 20 micron hard tempered aluminium foil.

Each blister tray contains 2, 4, 6, 8, 10, 12, 14, 16 20, 24, 30, 32, 36, 40 or 48 capsules. The blister trays are packed in a cardboard carton.

Not all packs are marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA0979/032/013

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