Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

TEST product

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Ibuprofen 200mg (as lysine salt).

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

White, film-coated capsule shaped tablet, printed with an identifying logo in black on one face.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an anti-inflammatory, analgesic and anti-pyretic for the relief of mild to moderate pain, such as headache, migraine, dental pain, feverishness, period pain, muscular strain and backache. For the symptomatic relief of fever, colds and influenza.

4.2 Posology and method of administration

Ciprofloxacin is indicated for the treatment of the following infections caused by sensitive bacteria (see section 4.4 and 5.1).
Consideration should be given to official guidance on the appropriate use of antibacterial agents. Adults

- *Upper and lower respiratory tract infections:* For example broncho- and lobar-pneumonia, exacerbations of chronic obstructive pulmonary disease, bronchitis (acute and chronic), acute exacerbation of cystic fibrosis, bronchiectasis, empyema, Gram-negative pneumonia (but *not* first-line therapy for pneumococcal pneumonia).

- Chronic suppurative otitis media
- Acute exacerbation of chronic sinusitis especially if these are caused by Gram-negative bacteria
- *Urinary tract infections:* For example urethritis (complicated and uncomplicated), cystitis, pyelonephritis, prostatitis, epididymitis.
- *Genital tractinfections:*

- gonococcal uretritis and cervicitis due to susceptible *Neisseria gonorrhoeae*

- epididymo-orchitis including cases due to susceptible *Neisseriagonorrhoeae*
- pelvic inflammatory disease including cases due to susceptible *Neisseriagonorrhoeae*

    - *Gastro-intestinal infections:* e.g. enteric fever, infective diarrhoea
    - *Intra-abdominalinfections*
    - *In*fections of the skin and soft tissue caused by Gram-negative bacteria
    - Malignant external otitis
    - Infections of the bones and joints
    - Prophylaxis of invasive infections due to *Neisseriameningitides*
    - Inhalation anthrax (post-exposure prophylaxis and curative treatment

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, 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 minimum effective dose for the shortest possible duration to control symptoms (See section 4.2, and GI and Cardiovascular risks below). Where prolonged therapy is required, patients should be reviewed regularly.

Patients allergic to or taking any other pain reliever, receiving regular medical treatment, the elderly and pregnant women should only take Nurofen Advance Tablets after consulting their doctor.

If symptoms persist for more than 3 days or worsen or if new symptoms occur, stop treatment at once and consult your doctor.

Other NSAIDs: The use of Nurofen Advance 200mg Tablets with concomitant NSAIDs including cyclooxygenase-2-selective inhibitors should be avoided (see section 4.5).

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 effects:
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 antiplatelet agents such as aspirin (see section 4.5).

When GI bleeding or ulceration occurs in patients receiving Nurofen Advance 200mg Tablets, 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 – undesirable effects).

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

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).

Dermatological effects: Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs (see 4.8).

Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first month of treatment. Nurofen Advance 200mg Tablets should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Exceptionally, varicella can be at the origin of serious cutaneous and soft tissue infectious complications. To date, the contributing role of NSAIDs in the worsening of these infections cannot be ruled out. Thus, it is advisable to avoid use of Nurofen Express 200mg Tablets in case of varicella.

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.

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 and oedema have been reported in association with NSAID therapy. Caution is required in patients with cardiac or hepatic impairment.

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.

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

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

4.5 Interaction with other medicinal products and other forms of interactions

Ibuprofen should be avoided in combination with:

Acetylsalicylic acid: Concomitant administration of ibuprofen and acetylsalicylic acid is not generally recommended unless low-dose Acetylsalicylic Acid (Aspirin) (not above 75mg daily) has been advised by a doctor because of the potential of increased adverse effects (see section 4.4). 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 effects of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional use (see section 5.1).

Other NSAIDs including cyclo-oxygenase-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 any of the following drugs as interactions have been reported:

Anti-hypertensives (ACE inhibitors and Angiotensin II Antagonists): reduced anti-hypertensive effect.

Diuretics: reduced diuretics effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

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

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

Lithium: decreased elimination of Lithium.

Methotrexate: decreased elimination of Methotrexate.

Cyclosporin: increased risk of nephrotoxicity with NSAIDs.

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

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

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

Anticoagulants: 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).

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: Increased risk of haematological toxicity when NSAIDs are given with Zidovudine. There is evidence of an increased risk of haemarthroses and haematoma in HIV (positive) 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.

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.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:

- Cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- Renal dysfunction, which may progress to renal failure with oligo-hydroaminosis;

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, in the last trimester of pregnancy use of ibuprofen is contraindicated.

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

No adverse effects known.

4.8 Undesirable effects

Possible side effects are those experienced with ibuprofen acid (maximum 1200mg Ibuprofen per day), in short-term use. In the treatment of chronic conditions, under long-term treatment, additional adverse events 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 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.

SystemOrganClass	**Frequency**	**AdverseEvents**
Bloodand Lymphatic System Disorders	Very rare	Haematopoietic disorders1
Immune System Disorders	Uncommon	Hypersensitivity with urticaria and pruritus 2
	Very rare	Swellingface,swollentongue,pharyngeal oedema,dyspnoea,tachycardia,and hypotension(anaphylaxis,angioedemaor severeshock)2
Nervous System Disorders	Uncommon	Headache
	Very rare	Asepticmeningitis 3
Ear and Labyrinth Disorders	Not Known	HearingImpaired
Cardiac Disorders	Not known	Cardiacfailureandoedema4
Vascular Disorders	Not known	Hypertension4
Respiratory,Thoracicand Mediastinal Disorders	Not known	Respiratory tract reactivity comprising asthma, bronchospasm or dyspnoea2
Gastrointestinal Disorders	Uncommon	Abdominal pain,nausea and dyspepsia 5
	Rare	Diarrhoea,flatulence,constipationandvomiting

	Very rare	Pepticulcer,gastrointestinalperforationor gastrointestinalhaemorrhage,melaena,and haematemesis6.Mouthulcerationand gastritis
	Not known	ExacerbationofcolitisandCrohn'sdisease7
Hepatobiliary Disorders	Very rare	Liverdisorder
	Not Known	Hepaticfunctionabnormal
Skin and Subcutaneous Tissue Disorders	Uncommon	Skinrash2
	Very rare	Bullousreactions,includingStevens-Johnson syndrome,erythemamultiformeandtoxic epidermalnecrolysis2
	Not Known	Rashmaculo-papular,erythema. Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome).
RenalandUrinary Disorders	Very rare	Acuterenalfailure8
Investigations	Very rare	Haemoglobindecreased
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 complication may occur during a varicella infection.

4.9 Overdose

Adverse drug reactions derived from post-marketing reports are included in the column frequency "not known"

System Organ Class	**Common 2:1/100 to <1/100**	**Uncommon 2: 1/1,000 to <1/100**	**Rare 2:1/10,000 to < 1/1,000**	**Very Rare < 1/10,000**	**Frequency not known (cannot be estimated from the available data)**
Infections		Mycotic	Antibiotic		

and Infestations		superinfections Candida infections	associated colitis *(very rarely associated with possible fatal outcome, see section 4.4)*		
Blood and Lymphatic System Disorders		Eosinophilia	Leukopenia Anaemia Neutropenia Leukocytosis Thrombocytopenia Thrombocythaemia	Haemolitic anaemia Agranulocytosis Pancytopenia (life-threatening) Bone Marrow suppression (life threatening)	
Immune System Disorders			Allergic reaction Allergic oedema anngiooedema	Anaphylatic reaction, Anaphylacctic shock (life-threatening) (see section 4.4) Serum sickness-like reaction	
Metabolism and Nutrition Disorders		Decreased appetite	Hyperglycaemia Hypoglycaemia (see section 4.4)		
Psychiatric Disorders		Psychomotor / hyperactivity / agitation	Confusion and disorientation Anxiety reaction Abnormal dreams Depression (potentially culminating in suicidal ideations/thoughts or suicidal attempts and completed suicide) (see	Psychotic reactions (potentially culminating in suicidal ideations/thoughts or suicidal attemps and acompleted suicide) (see section 4.4)	Mania, incl. hypomania

			section 4.4) Hallucinations		
Nervous System Disorders		Headache, Dizziness, Sleep disorders Taste disorders (*usually reversible upon discontinuation of treatment)*	Par- and Dysaesthesia Hypoaesthesia Tremor Seizures (incl. status epilepticus see section 4.4) Vertigo Somnolence	Migraine Disturbed coordination Gait disturbance Smell disorders Intracranial hypertension and pseudotumor celebri	Peripheral neuropathy and polyneuropathy (see section 4.4) Hyperaesthesia
Eye Disorders			Peripheral neuropathy and polyneuropathy (see section 4.4)	Peripheral neuropathy and polyneuropathy (see section 4.4)	
Cardiac Disorders			Tachycardia		Ventricular arrhythmia and torsades de pointes (reported predominantly in patients with risk factors for QT prolongation), ECG QT prolonged (see section 4.4 and 4.9)
Vascular Disorder			Vasodilation, Hypotension,	Vasculitis	

s			Syncope		
Respiratory, Thoracic and Mediastinal Disorders			Dyspnoea (*including asthmatic condition*)		
Gastro-intestinal Disorders	Nausea Diarrhoea	Vomiting Gastrointestinal and abdominal pain Dyspepsia Flatulence	Dysphagia	Pancreatitis	
Hepatobiliary Disorders		Transient increase in transaminases Increased bilirubin	Transient hepatic impairment Cholestatic icterus Jaundice Hepatitis (*non*	Liver necrosis (*veryrarely progressing tolife-threatening hepaticfailure*) (see section 4.4)	
Skin and Subcutaneous Tissue Disorders		Rash Pruritus Urticaria	Photosensitivity reactions (see section 4.4) Unspecific blistering	Petechiae Erythema multiforme Erythema nodosum Stevens-Johnson syndrome (potentially life-threatening) Toxic epidermal necrolysis (potentially life-threatening)	Acute generalised exanthematous pustulosis (AGEP) Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
Musculoskeletal, Connective Tissue		Musculoskeletal pain (e.g. extremity	Myalgia Arthritis Increased muscle tone and	Muscular weakness Tendonitis Tendon rupture	

and Bone Disorders		pain, back pain, chest pain) Arthralgia	cramping	(*predominantly Achillestendon)* (see section 4.4) Exacerbation of symptoms of myasthenia gravis (see section 4.4)	
Renal and Urinary Disorders		Renal impairment	Renal failure Haematuria Crystalluria (see section 4.4) Tubulointerstitial nephritis		
General Disorders and Administration Site Conditions		Asthenia Unspecific pain Feeling unwell Fever	Oedema Sweating (hyperhidrosis)		
Investigations		Transient increase in blood alkaline phosphatase	Prothrombin level abnormal Increased amylase		International normalised ratio increased (in patients with vitamin K antagonists)

Paediatric population

The incidence of arthropathy, mentioned above, is referring to data collected in studies with adults. In children, arthropathy is reported to occur commonly (see section 4.4).

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, Earlsfort Terrace, IRL - Dublin 2.Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Ibuprofen lysine is the lysine salt of ibuprofen, a propionic acid derivative, having analgesic, anti-inflammatory and antipyretic activity. Ibuprofen is a propionic acid derivative NSAID that has demonstrated its efficacy by inhibition of prostaglandin synthesis. The therapeutic effects of ibuprofen as a non-steroidal anti-inflammatory drug to reduce inflammatory pain, swellings and fever, are thought to result from inhibitory activity on prostaglandin synthetase. Furthermore, ibuprofen reversibly inhibits platelet aggregation.

Each tablet contains 342 mg of ibuprofen lysine. Following oral administration, ibuprofen lysine dissociates to ibuprofen acid and lysine. Lysine has no recognised pharmacological activity. The pharmacological properties of ibuprofen lysine, therefore, are the same as those of ibuprofen acid.

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).

5.2 Pharmacokinetic properties

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

Most pharmacokinetic data obtained following the administration of ibuprofen acid also apply to Nurofen Advance Tablets.

Ibuprofen is rapidly absorbed from the gastrointestinal tract. Peak plasma concentrations occur 1-2 hours after administration of ibuprofen acid. However, ibuprofen is more rapidly absorbed from the gastrointestinal tract following the administration of Nurofen Advance Tablets, with peak plasma concentrations occurring approximately 35 minutes after administration.

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

Following ibuprofen is metabolimin the liver (hydroxylation, carboxylation and conjugation) to two inactive metabolites these, together with unchanged ibuprofen, are excreted mainly by the kidney either as such or as conjugates (90%), but also with the bile. Excretion by the kidney is both rapid and complete.

The elimination half-life of ibuprofen acid is approximately 2 hours.

The drug is extensively bound to plasma proteins. Plasma-protein binding is about 99%. Ibuprofen diffuses into the synovial fluid.

Product specific pharmacokinetic properties:
The time to reach plasma concentration (Tmax) is greatly reduced for the ibuprofen lysine product compared with the equivalent ibuprofen acid product.
A pharmacokinetic study has reported a Tmax of 35 minutes for the ibuprofen lysine 342 mg product in the fasted state, compared with a time of 80 minutes for the equivalent strength ibuprofen acid product.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

test
abc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

A blister pack consisting of opaque, white 250µm polyvinyl chloride (PVC)/23µm polychlorotrifluoroethylene (Aclar) laminate heat sealed to 20µm aluminium foil.

Or

A blister pack consisting of opaque, white 250µm polyvinyl chloride (PVC)/40 gsm polyvinylidene chloride (PVdC) laminate heat sealed to 20µm aluminium foil.

The blisters are packed in cardboard cartons.

Pack sizes: 2, 4, 6, 10, 12, 20, 24, 28, 32, 36, 40 and 48 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Test MAH
28 Test
Test
Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER

PA22671/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22/01/2019

10 DATE OF REVISION OF THE TEXT

jan 2019