1. NAME OF THE MEDICINAL PRODUCT

Ibuprofen Twelve Plus Pain Relief 200mg/5ml oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml oral suspension contains 40 mg Ibuprofen.

Excipients with known effect: Maltitol liquid 500 mg/ml and 5.79 mg Sodium per 1 ml oral suspension.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension

White or off-white viscous suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Ibuprofen Oral Suspension is used for the short-term relief of: migraine, headaches, backache, dental pain, neuralgia and period pains as well as rheumatic and muscular pains, and pain of non-serious arthritic conditions.

Ibuprofen Oral Suspension relieves pain and reduces inflammation and temperature. It also relieves cold and flu symptoms.

4.2 Posology and method of administration

Posology

For oral administration and short-term use only. During short-term use, if symptoms persist or worsen the patient should be advised to consult a doctor.

Adults and children and adolescents between 12 and 18 years:
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.4).

If in children and adolescents between 12 and 18 years this medicinal product is required for more than 3 days, or if symptoms worsen, a doctor should be consulted.

If in adults the product is required for more than 10 days, or if the symptoms worsen, the patient should consult a doctor.

Adults, the elderly and children and adolescents aged 12 to 18 years:
Take 200-400mg (5-10ml), up to three times a day as required.

Leave at least four hours between doses and do not take more than 1200mg (30ml) in any 24 hour period.

Ibuprofen Oral suspension should not be used in children under 12 years of age

The package includes an oral syringe for oral administration of Ibuprofen Oral Suspension. The oral syringe is graduated in 0.25 ml steps up to 5 ml. 5 ml oral suspension corresponds to 200 mg ibuprofen. The bottle should be shaken vigorously before use.

Special patient groups

Elderly population:
No special dose adjustment is required in the elderly. Because of the possible undesirable effect profile (see section 4.4), the elderly should be monitored particularly carefully.

Method of administration

For oral administration. The bottle should be shaken vigorously before use.
The oral suspension can be taken with food. The package includes an oral syringe for oral administration or Ibuprofen oral suspension. The oral syringe is graduated in 0.25ml steps up to 5ml. 5ml oral suspension corresponds to 200mg ibuprofen.

4.3 Contraindications

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

Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema or urticaria) in response to ibuprofen, aspirin (acetylsalicylic acid) or other non-steroidal anti-inflammatory drugs (NSAIDs).

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

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

Severe hepatic failure (NYHA Class IV), severe renal failure or severe heart failure (see section 4.4).

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 control symptoms (see gastrointestinal and cardiovascular risks below).

Masking of symptoms of underlying infections:
Ibuprofen oral suspension 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 Ibuprofen 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.

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).

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

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

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

Renal:
Renal impairment as renal function may further deteriorate (see section 4.3 and 4.8). There is a risk of renal impairment in dehydrated children and adolescents.

Renal tubular acidosis and hypokalaemia may occur following acute overdose and in patients taking ibuprofen products over long periods it high doses (typically greater than 4 weeks), including doses exceeding the recommended daily dose.

Hepatic:
Hepatic dysfunction (see section 4.3 and 4.8)

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

Clinical trial and epidemiological data suggest that use of ibuprofen, particularly at high doses (2400 mg 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. ≤1200 mg daily) is associated with an increased risk of myocardial infarction.

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 Ibuprofen oral suspension. Kounis syndrome has been defined as cardiovascular symptoms secondary to an allergic or hypersensitive reaction associated with constriction of coronary arteries and potentially leading to myocardial infarction.

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

Gastrointestinal:

NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated (see section 4.8 – 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 warning symptoms or a previous history of GI events.

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

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

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

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

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 (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).

Advice for patients with sugar-related disorders:
This medicinal product contains maltitol liquid. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

Advice for patients on a controlled sodium diet:
This medicinal product contains 57.9 mg sodium (2.52 mmol) per 400 mg (10 ml) dose, equivalent to 2.9% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5 Interaction with other medicinal products and other forms of interaction

Ibuprofen should be avoided in combination with:

Aspirin (acetylsalicylic acid): Concomitant administration of ibuprofen and acetylsalicylic acid is not generally recommended because of the potential of increased adverse effects, unless low-dose aspirin (not above 75mg daily) has been advised by a doctor, (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 cardio protective effect 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 cyclooxygenase-2 selective inhibitors: Avoid concomitant use of two or more NSAIDs as this may increase the risk of adverse reactions (see section 4.4).

Ibuprofen (like other NSAIDs) should be used with caution in combination with:
Anticoagulants: NSAIDs may enhance the effects of anticoagulants, such as warfarin (see section 4.4).

Antihypertensives and diuretics: NSAIDs may diminish the effect of these drugs. Diuretics can increase the risk of nephrotoxicity of NSAIDs. 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 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 regular monitoring of renal function should be considered following initiation of combination therapy, and periodically thereafter.

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

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

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

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

Methotrexate: There is evidence for the potential increase in plasma levels of methotrexate.

Ciclosporin: Increased risk of nephrotoxicity.

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 haemothroses and haemotoma 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. During the first and second trimester of pregnancy, Ibuprofen Oral Suspension 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.

From the 20th week of pregnancy onward, Ibuprofen Oral Suspension 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 Oral Suspension should not be given unless clearly necessary. If Ibuprofen Oral Suspension 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 Oral Suspension for several days from gestational week 20 onward. Ibuprofen Oral Suspension 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 (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 Oral Suspension is contraindicated during the third trimester of pregnancy (see section 4.3).

Breast-feeding
In limited studies, ibuprofen appears in the breast milk in very low concentrations and is unlikely to affect the breast-fed infant adversely.

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. See section 4.4.

4.7 Effects on the ability to drive and use machines

None expected at recommended doses and duration of therapy.

4.8 Undesirable effects

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 to <1/10), uncommon (≥ 1/1000 to <1/100, rare (≥ 1/10,000 to <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 list of the following adverse events relates to those experienced with ibuprofen at OTC doses for short term use. In the treatment of chronic conditions, under long-term treatment, additional adverse events may occur. 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 is dependent on the dosage range and duration of treatment.

Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke), (see section 4.4).

System Organ Class	Frequency	Adverse Event
Blood and Lymphatic System Disorders	Very rare	Haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis)[1].
Immune System Disorders	Uncommon	Hypersensitivity reactions consisting of**:** Urticarial and pruritus[2]
	Very rare	Severe hypersensitivity reactions. Symptoms could be: facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension, (anaphylaxis, angiodema or severe shock)[2]
Respiratory, Thoracic and Mediastinal Disorders	Not Known	Respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea[2].
Nervous System Disorders	Uncommon	Headache
	Very rare	Aseptic meningitis[3].
Cardiac Disorders	Not Known	Cardiac failure and oedema[4] Kounis syndrome
Vascular Disorders	Not Known	Hypertension[4]
Gastrointestinal Disorders	Uncommon	Abdominal pain, nausea, dyspepsia[5]
	Rare	Diarrhoea, flatulence, constipation and vomiting
	Very rare	Peptic ulcer, perforation or gastrointestinal haemorrhage, melaena, haemotemesis[6], sometimes fatal, particularly in the elderly. Ulcerative stomatitis, gastritis. Exacerbation of colitis and Crohn's disease[7] (section 4.4).
Hepatobiliary Disorders	Very rare	Liver disorders
Skin and Subcutaneous Tissue Disorders	Uncommon	Various skin rashes[2]
	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
	Not Known	Ureteric colic, dysuria, renal tubular acidosis[9]
Investigations	Very rare	Decreased haemoglobin levels
Infections and infestations	Not Known	Exacerbation of infections related inflammation has been described, in exceptional cases, severe skin infections and soft tissue complications may occur during a varicella infection.
Metabolic and Nutrition Disorders	Not Known	Decreased Appetite Hypokalaemia[9]

Description of Selected Adverse Reactions

[1]First signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.

[2]Hypersensitivity reactions have been reported following treatment with ibuprofen. These may consist of (a) nonspecific allergic reactions and anaphylaxis, (b) respiratory tract activity comprising asthma, aggravated asthma, bronchospasm, dyspnoea or (c) assorted skin disorders, including rashes of various types pruritus, urticaria, purpura, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis 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 trial and epidemiological data suggest that use of ibuprofen (particularly at high doses 2400 mg 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.

[8]Especially in long-term use, associated with increased serum urea and oedema. Also includes papillary necrosis.

[9]Renal tubular acidosis and hypokalaemia have been reported in the post marketing setting typically following prolonged use of the ibuprofen component at higher than recommended doses.

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

4.9 Overdose

In children ingestion of more than 400mg/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 diarrhea. Tinnitus, headache and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as drowsiness, occasionally excitation and disorientation or coma. Occasionally patients develop convulsions. In serious poisoning metabolic acidosis may occur and the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics.

Management:

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

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

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

Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose aspirin (acetylsalicylic acid) on platelet aggregation when they are dosed concomitantly. Some pharmacodynamics studies show that when single doses of ibuprofen 400mg were taken within 8 hours before or within 30 minutes after immediate release aspirin 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

Absorption
Ibuprofen is rapidly absorbed following administration and is rapidly distributed throughout the whole body. The excretion is rapid and complete via the kidneys.
Distribution
Maximum plasma concentrations are reached 45 minutes after ingestion if taken on an empty stomach. When taken with food, peak levels are observed after 1 to 2 hours. These times may vary with different dosage forms.
Elimination
Elimination half-life is approximately 2 hours.
In limited studies, ibuprofen appears in the breast milk in very low concentrations.

5.3 Preclinical safety data

The subchronic and chronic toxicity of ibuprofen in animal experiments showed up mainly in form of lesions and ulcerations in the gastro-intestinal tract.
In vitro and in vivo studies gave no clinically relevant evidence of a mutagenic potential of ibuprofen. In studies in rats and mice no evidence of carcinogenic effects of ibuprofen was found. Ibuprofen inhibited ovulation in rabbits and impaired implantation in various animal species (rabbit, rat, mouse). Experimental studies in rat and rabbit have shown that ibuprofen crosses the placenta. Following administration of maternotoxic doses, an increased incidence of malformations (ventricular septal defects) occurred in the progeny of rats.
The active substance ibuprofen shows an environmental risk for fish.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate (E211),
Citric acid anhydrous,
Sodium citrate,
Saccharin sodium,
Sodium chloride,
Hypromellose,
Xanthan gum,
Maltitol liquid,
Glycerol (E422),
Thaumatin (E957),
Strawberry flavour (natural flavouring preparations, maize maltodextrin, triethyl citrate (E-1505), propylene glycol (E-1520) and benzyl alcohol),
Purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

After first opening: 6 months

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Amber coloured polyethylene terephthalate (PET) bottles of 30 ml and 100 ml with a child-resistant closure, fitted with a low density polyethylene stopper.

The product is supplied with a 5 ml oral syringe, comprising of a high-density polyethylene piston and a polypropylene barrel. The oral syringe is graduated in 0.25 ml steps up to 5 ml.

Not all pack-sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

No special requirements

7 MARKETING AUTHORISATION HOLDER

Aspire Pharma Ltd
Unit 4 Rotherbrook Court
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Petersfield
Hampshire
GU32 3QG
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8 MARKETING AUTHORISATION NUMBER(S)

PL35533/0034

9 DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

Date of latest renewal: 29/11/2017

10 DATE OF REVISION OF THE TEXT

05/03/2024