SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Galprofen Long Lasting Ibuprofen Capsules
Asda Long Lasting Pain Relief
Morrisons Long Lasting Pain Relief
Wilko Long Lasting Pain Relief
Superdrug Long Lasting Pain Relief
Boots Ibuprofen Long Lasting Capsules 200mg
Lloydspharmacy Ibuprofen 200mg Long Lasting Capsules
Teva Ibuprofen 200mg Long lasting Capsules
Co-op Ibuprofen 200mg Long Lasting Capsules
Tesco Health Long Lasting Pain Relief, 200mg Modified Release Capsules, Hard
Essential Waitrose & Partners Long Lasting Pain Relief 200mg Modified Release Capsules
Sainsbury's Healthcare Long Lasting Pain Relief 200mg Modified Release Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 200mg
For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Modified-Release Capsule, Hard. [Modified-Release Capsule]
Blue/Clear capsules containing white coated beads.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Rheumatic or muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea (period pain), feverishness, symptoms of colds and influenza.

4.2 Posology and method of administration

For oral administration and short term use only:

Adults, the elderly and children over 12 years:
The minimum effective dose should be used for the shortest time necessary to relieve symptoms.

Swallow 400mg (2 capsules), preferably with water, each morning and evening, as required. Do not take more than 800mg (4 capsules) in any 24 hour period.

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

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

Not to be given to children under 12 years.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.4).

4.3 Contraindications

Hypersensitivity to ibuprofen or any of the excipients in the product.

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

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

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

Severe heart failure (NYHA Class IV), renal failure or hepatic failure (see section 4.4 Special Warnings and Precautions for Use).

Last trimester of pregnancy (see section 4.6 Pregnancy and lactation).

4.4 Special warnings and precautions for use

Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms (see GI and cardiovascular risks below).

The elderly have an increased frequency of adverse reactions to NSAID's especially gastrointestinal bleeding and perforation which may be fatal.

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

Other NSAIDs:
The use of Ibuprofen 200mg Long Lasting Capsules with concomitant NSAIDs including cyclooxengenase-2-selective inhibitors should be avoided.

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

Renal:

Renal impairment as renal function may further deteriorate (see section 4.3 Contraindications and section 4.8 Undesirable effects).

There is risk of renal impairment in dehydrated adolescents.

Hepatic:
Hepatic dysfunction (see section 4.3 Contraindications and section 4.8 Undesirable effects).

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 ibuprofen. 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 on 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 anytime during treatment, with or without 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 Contraindications) 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 gastrotoxicity or bleeding, such as oral corticosteroids, or anticoagulants such as warfarin, selective serotonin reuptake inhibitors, or anti-platelet agents such as aspirin (see section 4.5 Interactions).

Where GI bleeding or ulceration occurs in patients receiving ibuprofen, 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 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 Undesirable Effects). 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:
This medicine 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 this medicine 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.

The label will include:
Please read the enclosed leaflet carefully before use.

Do not take if you:
- have or have had a stomach ulcer, perforation or bleeding of the stomach
- are allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers
- are taking other NSAID painkillers, or aspirin with a daily dose above 75mg

If you are pregnant do not take this product and ask your doctor for advice

Talk to a pharmacist or your doctor before taking this product if you:
- are elderly
- have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney, stomach or bowel problems
- are a smoker

Do not exceed the stated dose. Keep all medicines out of the reach and sight of children. Talk to a doctor or pharmacist if you do not get better or if new symptoms occur.

4.5 Interactions with other medicinal products and other forms of interaction

Ibuprofen should not be used in combination with:

Aspirin: Unless low-dose aspirin (not above 75mg daily) has been advised by a doctor, as this may increase the risk of adverse reactions (see section 4.3 Contraindications).

Other NSAIDs including cyclooxegenase-2 selective inhibitors: Avoid concomitant use of two or more NSAIDs as this may increase the risk of adverse effects (see section 4.3 Contraindications).

Ibuprofen should be used with caution in combination with:
Anticoagulants: NSAIDs may enhance the effects of anti-coagulants, such as warfarin (see section 4.4 Special Warnings and Precautions for Use).

Antihypertensives and diuretics: NSAIDs may diminish the effect of these drugs. Diuretics can increase the risk of nephrotoxicity to NSAID's.

Corticosteroids: Increased risk of gastrointestinal ulceration or bleeding (see section 4.4 Special Warnings and Precautions for Use).

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

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

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

Methotrexate: There is a potential for an increase in plasma methotrexate.

Cyclosporin: Increased risk of nephrotoxicity

Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone. Administration of NSAID's can reduce the effect of mifepristone.

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

Zidovudine: Increased risk of haematological activity 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 NSAID's can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increase risk of developing convulsions.

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).

4.6 Fertility, pregnancy and lactation

From the 20th week of pregnancy onward, ibuprofen use may cause oligohydramnios resulting from foetal renal dysfunction. This may occur shortly after treatment initiation and is usually reversible upon discontinuation. In addition, there have been reports of ductus arteriosus constriction following treatment in the second trimester, most of which resolved after treatment cessation. Therefore, during the first and second trimester of pregnancy, ibuprofen should not be given unless clearly necessary. If ibuprofen is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible. Antenatal monitoring for oligohydramnios and ductus arteriosus constriction should be considered after exposure to ibuprofen for several days from gestational week 20 onward. Ibuprofen should be discontinued if oligohydramnios or ductus arteriosus constriction are found.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:
- cardiopulmonary toxicity (premature constriction/closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction (see above);

the mother and the neonate, at the end of pregnancy, to:
- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses;
- inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, ibuprofen is contraindicated during the third trimester of pregnancy (see sections 4.3 and 5.3).

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

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 following list of adverse effects 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 effects may occur.

The adverse effects have been listed in order of decreasing frequency, using the following convention:

Very Common (≥1/10); Common (≥1/100 to <1/10); Uncommon (≥1/1,000 to <1/100); Rare (≥1/10,000 to <1/1,000); Very Rare (<1/10,000); Not Known (cannot be estimated form the available data).

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, unexplained bleeding and bruising.

Immune System Disorders:
Uncommon: Hypersensitivity reactions with urticaria and pruritus.
Very rare: Severe hypersensitivity reactions. Symptoms could include: facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema or severe shock).

Not Known: Non-specific allergic reactions.
Respiratory tract reactivity (e.g. asthma, aggravated asthma and bronchospasm).
Various skin reactions including exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).
In patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease) during treatment with ibuprofen, single cases of symptoms of aseptic meningitis, such as stiff neck, headache, nausea, vomiting, fever or disorientation have been observed (see section 4.4 Special Warnings and Precautions for Use).

Nervous System Disorders:
Uncommon: Headache.
Vary rare: Aseptic Meningitis – single cases have been reported very rarely.

Cardiac Disorders and Vascular Disorders:
Not known: Oedema, hypertension, cardiac failure and Kounis syndrome.
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).

Gastrointestinal Disorders:
The most commonly observed side effects of ibuprofen are gastrointestinal in nature.
Uncommon: Abdominal pain, nausea and dyspepsia.
Rare: Diarrhoea, flatulence, constipation and vomiting.
Very rare: Peptic ulcer, perforation or gastrointestinal haemorrhage, melaena, haematemesis, sometimes fatal, particularly in the elderly, ulcerative stomatitis, gastritis.

Not Known: Exacerbation of ulcerative colitis and Crohn's disease (see section 4.4 Special Warnings and Precautions for Use).

Hepatobiliary Disorders:
Very rare: Liver disorders.

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) and 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.

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 at: www.mhra.gov.uk/yellowcard or search 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 diarrhoea. 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.

Prolonged use at higher than recommended doses may 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).

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.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids, propionic acid derivatives.
ATC code: M01A E01

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 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 (81 mg), 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.

With immediate release formulations of ibuprofen, maximum plasma concentrations are reached 45 minutes after ingestion if taken on an empty stomach. When taken with food, high peak levels are observed after 1 to 2 hours. These times may vary with different dosage forms. The sustained release product releases drug more slowly, with a lower peak level being reached in plasma about 4 hours after dosage.

The half life of ibuprofen is about 2 hours. For sustained release formulations, the drug concentration in plasma decays more slowly and remains at significant levels 12 hours after dosing. With continuous dosing the peak/trough ratio is markedly less than with immediate release formulations of ibuprofen.

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

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

Microcrystalline Cellulose

Eudragit NE30D

Hypromellose

Talc

Collodial Silicon Dioxide

Shell

Gelatin

Titanium Dioxide (E171)

Patent Blue V (E13l)

Erythrosine (El27)

6.2 Incompatibilities

None

6.3 Shelf life

3 years

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Blister packs comprised of Al/PVC strips enclosed in an outer carton containing 6, 8, 12, 16 capsules.

6.6 Special precautions for disposal

Not applicable

7. MARKETING AUTHORISATION HOLDER

Galpharm Healthcare Limited
Wrafton
Braunton
Devon
EX33 2DL
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 16028/0120

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/07/1996 / 13/01/2006

10 DATE OF REVISION OF THE TEXT

26/01/2024