Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nurofen 200mg Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Ibuprofen 200mg.

Excipients: Contains sucrose

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Coated tablet.

Product imported from the UK:
White round sugar-coated tablet with “NUROFEN” imprinted in black.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

For the symptomatic treatment of osteoarthritis.

4.2 Posology and method of administration

Adults and children over 12 years: Initial dose is 400mg and subsequently if necessary, 200 to 400mg every four hours with a maximum of 1200mg in a 24 hour period.

Not suitable for children under 12 years of age.

For oral administration.

NSAIDs should be used with particular caution in elderly patients who are more prone to adverse events.

4.3 Contraindications

Severe heart failure.

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 history of hypersensitivity reactions (e.g. bronchospasm, rhinitis, urticaria) in response to ibuprofen, aspirin or non-steroidal anti-inflammatory drugs.

Use in children under 12 years of age.

4.4 Special warnings and precautions for use

The use of Nurofen 200 mg Coated Tablets with concomitant NSAIDs including cycloosygenase-2 selective inhibitors should be avoided.

Undesirable effects may be minimised by using the minimum effective dose for the shortest duration necessary to control symptoms (See section 4.2, and GI and cardiovascular risks below).

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).

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 pervious 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 anti-platelet agents such as aspirin (see Section 4.5).

When GI bleeding or ulceration occurs in patients receiving Nurofen 200 mg Coated 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).

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.

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

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 200 mg Coated Tablets should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

The labelling should state: If symptoms persist for more than 3 days or you experience any other symptoms unrelated to the original condition, discontinue treatment immediately and consult your doctor.

In patients with renal, cardiac or hepatic impairment, caution is required since the use of NSAIDs may result in deterioration of renal function.

Elderly patients are at increased risk of the consequences of adverse events. Prolonged use of NSAIDs in the elderly is not recommended.

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

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

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

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.

4.5 Interaction with other medicinal products and other forms of interaction

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

Anti-coagulants: NSAIDs may enhance the effects of anticoagulants, such as warfarin (see section 4.4).
Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding (see section 4.4).

Care should be taken in patients treated with any of the following drugs as interactions have been reported:

Anti-hypertensive: reduced anti-hypertensive effect.

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

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

Lithium: decreased elimination of lithium.

Methotrexate: decreased elimination of methotrexate

Cyclosporin: increased risk of nephrotoxicity with NSAIDs.

Other NSAIDs: avoid concomitant use of two or more NSAIDs.

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

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

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

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. However, the limitations of these data and the uncertainties regarding extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use (see section 5.1).

4.6 Fertility, pregnancy and lactation

Whilst no teratogenic effects have been demonstrated in animal experiments, the use of Nurofen during pregnancy should, if possible, be avoided. The onset of labour may be delayed and duration of labour increased.

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

4.7 Effects on ability to drive and use machines

No adverse affects known.

4.8 Undesirable effects

The most likely side effects are dyspepsia, gastrointestinal intolerance and bleeding. Skin rashes, including pruritus, erythema, urticaria, maculopapular rash and other allergic reactions have been reported. Very rarely erythema multiforme has been reported. Thrombocytopenia has also been reported.

Gastrointestinal: 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 – Special warnings and precautions for use) have been reported following administration. Less frequently, gastritis has been observed.

Cardiovascular: Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment. Cardiovascular and cerebrovascular effects: Clinical trial and epidemiological data suggest that use of ibuprofen , particularly at high doses (2400mg daily) and in long term treatment may be associated with a small increased risk of arterial thrombotc events (for example myocardial infarction or stroke) (see section 4.4).

Skin reactions: Bullous reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis (very rare).

4.9 Overdose

Symptoms include nausea, vomiting, dizziness, hypotension and, rarely, loss of consciousness. Large overdoses are generally well tolerated when no other drugs are involved. No specific antidote is available and supportive therapy is indicated. Treatment consists of gastric lavage and if necessary correction of serum electrolytes.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Experimental data suggests that ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. In one study, when a single dose of ibuprofen 400mg was taken within 8 h before or within 30 min after immediate release aspirin dosing 81mg, a decreased effect of ASA on the formation of thromboxane or platelet aggregation occurred. However, the limitations of these data and the uncertainties regarding extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use.

5.2 Pharmacokinetic properties

Ibuprofen is rapidly absorbed from the gastrointestinal tract, peak serum concentrations occurring 1 to 2 hours after administration. The elimination half life is approximately 2 hours.

Ibuprofen is metabolised in the liver to two inactive metabolites and these together with unchanged Ibuprofen are excreted by the kidney either as such or as conjugates. Excretion by the kidney is both rapid and complete.

Ibuprofen is extensively bound to plasma proteins.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sodium Citrate
Talc
Croscarmellose Sodium
Stearic Acid
Titanium Dioxide (E171)
Silicon Dioxide
Acacia
Carmellose Sodium
Sodium Larylsulphate
Macrogol 6000
Black Ink: (Shellac, Iron oxide black (E172), and Propylene Glycol)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister strips and outer carton of the product on the market in the country of origin.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Over-labelled outer cardboard carton containing one blister strip containing 12 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

G & A Licensing Ltd
Ballymurray
Co. Roscommon
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1447/51/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th November 2009

10 DATE OF REVISION OF THE TEXT