Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nurofen Micro-Granules 400 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen Ph. Eur. 400mg.

3 PHARMACEUTICAL FORM

Effervescent granules

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an anti-inflammatory and analgesic in the short term relief of muscular strain, backache, period pain and dental pain.

4.2 Posology and method of administration

For oral administration.

Adults and children over 12 years:
Initial dose contents of one sachet. Place contents of one sachet in a glass and half fill with water and stir. Drink immediately. Then, if necessary, one sachet every 4 hours. Do not take more than 3 sachets in 24 hours.

Not suitable for children under 12 years of age.

Elderly: see statements in Section 4.4.

4.3 Contraindications

Patients with existing, or a history of peptic ulceration, or other gastrointestinal disorders.

Hypersensitivity to any of the constituents, aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs).

Patients with a history of bronchospasm, rhinitis, urticaria associated with aspirin or other NSAID.

4.4 Special warnings and precautions for use

If symptoms persist for more than 3 days or any other symptoms not related to original condition, are experienced, the treatment should be discontinued immediately and a doctor should be consulted.

Undesirable effects may be reduced by using the minimum effective dose for the shortest possible duration.

Caution is required in patients with renal, cardiac or hepatic impairment. In patients with renal impairment, renal function should be monitored since it may deteriorate following the use of any NSAID.

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

Elderly patients are particularly susceptible to the adverse effects of NSAIDs. Prolonged use of NSAIDs in the elderly is not recommended. Where prolonged therapy is required, patients should be reviewed regularly.

Each sachet contains 132mg sodium (or 6mEq, equivalent to 335mg sodium chloride salt). This should be considered in patients whose overall intake of sodium must be markedly restricted.

Do not exceed 3 sachets daily.

4.5 Interaction with other medicinal products and other forms of interaction

It is considered unsafe to take NSAIDs in combination with warfarin or heparin unless under direct medical supervision.

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

Anti-hypertensives:
reduced anti-hypertensives 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.

Corticosteroids:
increased risk of gastrointestinal bleeding.

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 risk of hypoglycaemia.

4.6 Pregnancy and lactation

Studies in animals and experience to date in humans have not revealed any evidence of teratogenicity. However, use during pregnancy should if possible, be avoided. 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 effects known.

4.8 Undesirable effects

Gastro-intestinal:
abdominal pain, nausea and dyspepsia. Occasionally peptic ulcer and gastro-intestinal bleeding.

Skin:
pruritus, urticaria, rarely erythema multiforme, exfoliative dermatitis and epidermal necrolysis have been reported with ibuprofen.

Renal:
papillary necrosis which can lead to renal failure.

Others:
hepatic dysfunction, headache, dizziness, hearing disturbance. Rarely thrombocytopenia.

4.9 Overdose

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

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.

5.2 Pharmacokinetic properties

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

Ibuprofen is metabolised in the liver to two major 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

There are no preclinical safety data of relevance to the consumer.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Croscarmellose sodium
Malic acid
Sodium saccharin
Sucrose
Povidone (K29 – 32)
Sodium bicarbonate
Anhydrous sodium carbonate
Orange flavour 57.403/TP05/51 Firme
Sodium lauryl sulphate

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Not applicable.

6.5 Nature and contents of container

A paper/polythene/aluminium/polythene laminate sachet, two, six, twelve or twenty four sachets per carton.

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

Place contents of one sachet in a glass, half fill with water and stir.
Drink Immediately.

7 MARKETING AUTHORISATION HOLDER

Crookes Healthcare Limited
1, Thane Road West
Nottingham
NG2 3AA
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 43/6/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 August 2002

10 DATE OF REVISION OF THE TEXT

October 2004