

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nurofen Caplets 200 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Ibuprofen 200 mg.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Coated Tablet

A white to off-white, sugar-coated caplet with the word 'NUROFEN' printed in black on one face.

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, period pain, muscular strain and for the management of the symptoms of head colds and influenza.

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.

4.3 Contraindications

Hypersensitivity to any of the constituents.

Patients with a history of, or existent peptic ulcer or other gastrointestinal disorder.

Use in patients hypersensitive to aspirin, or with bronchospasm, asthma, rhinitis or urticaria associated with aspirin or other anti-inflammatory drugs.

Use in children under 12 years of age.

4.4 Special warnings and precautions for use

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

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 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.

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-hypertensive effect.

Diuretics:

Reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

Cardiac glycosides:

NSAIDs may exacerbate cardiac failure, reduce glomerular filtration rate - 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 aminoglycosides and increased plasma concentrations.

Probenecid:

Reduction in metabolism and elimination of NSAIDs and metabolites.

Oral hypoglycemic agents:

Inhibition of metabolism of sulfonylurea drugs, prolonged half-life and increased risk of hypoglycaemia.

Anticoagulants:

There is limited evidence of enhancement of oral anticoagulants.

4.6 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 effects known.

4.8 Undesirable effects

Gastro-intestinal:

Abdominal pain, nausea and dyspepsia. Occasionally peptic ulcer and gastro-intestinal bleeding.

Skin:

Pruritus, urticaria. Rarely 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 and rarely thrombocytopenia.

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.

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 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
Silica Collaidal Anhydrous
Acacia
Carmellose Sodium
Sodium Laurylsulphate
Macrogol 6000
Printed ink:
Opacode S-8152 HV Black [shellac, iron oxide black trace, soya lecithin, simeticone]

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Blister pack consisting of blisters of 250 Fm opaque PVC/40 gsm PVdC heat sealed to 20 Fm aluminium foil. The blisters trays are packed in cardboard cartons containing, 2, 4, 6, 10, 12, 16, 20, 24, 28, 32, 36, 40 and 48 caplets.

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

Crookes Healthcare Ltd
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8 MARKETING AUTHORISATION NUMBER

PA43/6/7

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th December 1999

Date of last renewal: 10th December 2004

10 DATE OF REVISION OF THE TEXT

November 2005