Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ibucaps Ibuprofen 200mg Soft Gelatin Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen BP 200mg.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, soft
Oval capsule with a translucent red gelatin shell containing a clear liquid with an identifying motif in white.

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, feverishness, period pain, muscular strain, backache and for the management of the symptoms of head cold and influenza.

4.2 Posology and method of administration

For oral administration. Do not chew.

Adults and children over 12 years:
Initial dose two capsules taken with water and subsequently if necessary, one or two capsules every four hours with a maximum of six capsules in any 24 hours.

Not for use by children under 12 years of age.

Elderly:
No special dosage modifications are required.

4.3 Contraindications

Hypersensitivity to any of the constituents, aspirin, or other non steroidal anti-inflammatory drugs (NSAIDs).
Patients with a history of, or existing peptic ulceration or other gastrointestinal disorder.
Patients with a history of bronchospasm, asthma, rhinitis, or urticaria associated with aspirin or other NSAIDs.
Use in children under 12 years of age.

4.4 Special warnings and precautions for use

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

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

Caution is required in patients with renal, cardiac or hepatic impairment since function may deteriorate. The dose should be as low as possible and renal function monitored.

Asthma sufferers, anyone allergic to or taking any other painkiller or receiving regular treatment, pregnant women or patients with hereditary fructose intolerance should only take Ibucaps Ibuprofen 200mg Soft Gelatin capsules after consulting their doctor.

Elderly patients are particular 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.

If symptoms persist for more than 3 days or the patient experiences any other symptoms unrelated to the original condition treatment should be discontinued and the patient should consult their doctor.

Side effects include gastrointestinal disturbances and rashes. Bleeding and peptic ulceration and thrombocytopenia have also been reported.

4.5 Interaction with other medicinal products and other forms of interaction

It is considered unsafe to take NSAIDs in combination with warfarin of 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 affect. Diuretics can increase the risk of nephrotoxicity of NSAIDs.
- Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce glomerular filtration rate 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: concomitant use of two of 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.
- 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 Ibucaps Ibuprofen 200mg Soft Gelatin Capsules 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 concentration and is unlikely to affect the breast-fed infant adversely.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Hypersensitivity reactions have been reported following treatment with ibuprofen. These may consist of (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract activity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, more rarely, bullous dermatoses (including epidermal necrolysis and erythema multiforme).

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

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, 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 of 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 are thought to result from inhibitory activity on prostaglandin synthetase.

5.2 Pharmacokinetic properties

Ibucaps Ibuprofen 200mg Soft Gelatin Capsules consist of 200mg ibuprofen dissolved in a hydrophilic solvent inside a gelatin shell. On ingestion the gelatin shell disintegrates in the gastric juice (pH 1.5) releasing the solubilising ibuprofen ready for absorption.

Ibuprofen is well absorbed from the gastrointestinal tract, is extensively bound to plasma proteins and diffuses into the synovial fluid.

The median peak plasma concentration for Ibucaps is reached quickly, 70 minutes after administration. When taken with food, peak plasma levels may be delayed.

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

Elimination half-life is approximately 2 hours.

No significant difference in pharmacokinetic profile is observed in the elderly.

5.3 Preclinical safety data

There are no preclinical safety data of relevance additional to that contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyethylene glycol 600
Vitamin E TPGS
Povidone
Gelatin
Maltitol Liquid
Sorbitol 76% solution
Purified Water
Ponceau 4R (E124)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

PVC blister pack only.
Do not store above 25^{o}C. Keep in outer carton.

6.5 Nature and contents of container

The capsules are packed in blister push-through pockets formed from white opaque 250micrometres PVC/60 gsm PVdC laminate heat sealed to 20 micrometres aluminium foil.
The blister trays are packed in a cardboard carton.

Pack sizes :2,4,6,8,10,12,16,20,24,30,40 and 48 capsules.
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

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 1121/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 September 2005

10 DATE OF REVISION OF THE TEXT