Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bufigen Tablets 200 mg.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 200 mg of Ibuprofen B.P.

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of various arthroses such as rheumatoid arthritis and osteoarthritis, fibrositis, ankylosing spondylitis, and other muscular syndromes, such as low back pain, soft tissue trauma and various inflammations of tendon, joint capsules and ligaments.

Bufigen may be used for its analgesic effect in the relief of mild to moderate pain.

4.2 Posology and method of adminstration

Bufigen tablets are for oral administration.

Adults:

The usual daily dose is 1200 to 1800 mg daily in divided doses. Some patients can be maintained on 600-1200 mg. The maximum recommended daily dose is 2400 mg.

Elderly:

No special dosage modifications are required for elderly patients, unless hepatic or renal function is impaired, in which case dosage should be assessed individually.

Children:

20 mg per kg of body weight daily in divided doses for children over 30 kg body weight. The total dose in children weighing less than 30 kg should not exceed 500 mg in 24 hours. Not recommended for children weighing less than 7kg.

4.3 Contraindications

Bufigen should not be administered to patients with active peptic ulceration. Bufigen should not be used in patients with a known hypersensitivity to ibuprofen, nor should it be given to patients in whom ibuprofen, aspirin or other non-steroidal anti-inflammatory drugs induce the symptoms of bronchospasm, rhinitis or urticaria.

4.4 Special warnings and precautions for use

Non-steroidal anti-inflammatory drugs have been reported to cause nephrotoxicity in various forms: interstitial nephritis, nephrotic syndrome and renal failure. Caution is required in patients with renal, cardiac or hepatic impairment, since the use of non-steroidal anti-inflammatory drugs may result in deterioration of renal function. The dose should be kept as low as possible and renal function should be monitored in these patients.

Bufigen should be used with great caution in patients with a history or evidence of peptic or other intestinal ulceration, cardiovascular disease or bleeding disorders.

Care is also required when using ibuprofen in patients with a history of asthma or bronchospasm, as bronchospasm may be precipitated in such patients.

4.5 Interaction with other medicinal products and other forms of interaction

Bufigen should be used only with caution in patients receiving oral anticoagulants or thiazide diuretics.

4.6 Pregnancy and lactation

Ibuprofen should only be used during pregnancy if considered essential by the physician. Studies in animals and experience to date in human beings have not revealed evidence of teratogenicity. Ibuprofen appears in 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

Patients who experience dizziness or blurred vision whilst taking N.S.A.I.D.s. should refrain from driving or operating machinery.

4.8 Undesirable effects

Possible side-effects include gastrointestinal disturbances occasionally leading to gastrointestinal or peptic ulceration, dizziness, headache, rash, pruritus, oedema, blurred vision, hypersensitivity. Thrombocytopenia, abnormal liver function and impaired renal function have also been reported.

4.9 Overdose

There is no specific antidote to ibuprofen. In acute overdosage, the stomach should be emptied by gastric aspiration and lavage, or by inducing emesis. Treatment is symptomatic and supportive; blood electrolytes should be corrected if necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Bufigen contains ibuprofen, a non-steroidal anti-inflammatory drug derivative of phenylpropionic acid. Bufigen has both analgesic and anti-inflammatory effects.

5.2 Pharmacokinetic properties

Ibuprofen is absorbed rapidly after oral administration, is strongly bound to plasma proteins and has a serum half-life of about two hours. Ibuprofen is excreted mainly in urine as metabolites.

5.3 Preclinical safety data

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
Maize starch
Lactose
Microcrystalline cellulose
Povidone
Colloidal silicon dioxide
Sodium starch glycollate

Sugar Coating

Shellac, Povidone, Acetylated glycerides, Calcium carbonate, Sucrose, Titanium dioxide, Erythrosine lake, Sodium benzoate, Polyethylene glycol 6000, Shellac vegetable carbon, Antifoam, Acacia, Talc, Methyl hydroxybenzoate, Propyl hydroxybenzoate, Maize starch.

6.2 Incompatibilities

None

6.3 Shelf Life

4 years.

6.4 Special precautions for storage

Do not store above 25^0C.
Protect from light.

6.5 Nature and contents of container

Polypropylene securitainers with tamper evident polypropylene caps.
Pack sizes: 500 tablets.

6.6 Instructions for use and handling

None

7 MARKETING AUTHORISATION HOLDER

Antigen Pharmaceuticals Limited
Roscrea
County Tipperary

8 MARKETING AUTHORISATION NUMBER

PA 73/63/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first approval: 13th May 1981.

Date of last renewal: 13th May 2001.

10 DATE OF REVISION OF THE TEXT

February 2002.