Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ibuprofen 200 mg / Codeine Phosphate 12.8 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Ibuprofen 200 mg and Codeine Phosphate 12.8 mg.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet
A white, capsule-shaped tablet embossed with the logo ‘N +’ on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Arthritic pain

Short to medium term use in acute and chronic painful arthroses and rheumatoid ‘flare’, including relief from severe pain in osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and sero-negative arthropathies.

Other inflammatory disorders

Short term relief from severe pain associated with inflammatory disorders such as bursitis, capsulitis of the shoulder, tendinitis, tenosynovitis.

Cancer pain
For use in patients where the pain may be controlled by this combination prior to the administration of morphine.

Dysmenorrhoea
Short term treatment of severe pain associated with dysmenorrhoea.

Severe pain in other clinical conditions
Short term treatment of severe pain in clinical conditions such as dental extraction, post-operative pain (including post-episiotomy), migraine, sprains, strains and low back pain.

4.2 Posology and method of administration

Route of administration
Oral.

Adults
One or two tablets every four to six hours.

Children under 12 years
Not recommended.

Elderly
No special dosage recommendations are required for elderly patients unless renal or hepatic function is impaired, in which case dosage should be assessed individually. NSAIDs (non steroidal anti-inflamatory drugs) should not be used continuously over prolonged periods in the elderly for the management of arthroses without careful supervision.

4.3 Contraindications

Respiratory depression, hypersensitivity to ibuprofen or codeine, a history of peptic ulceration, chronic constipation.

4.4 Special warnings and precautions for use

1. Use with caution in patients with gastrointestinal disease. If given to patients receiving anti-coagulant therapy, pro-thrombin time should be monitored daily for the first few days of combined treatment. Use with caution in those with hypotension, hypothyroidism, hepatic and /or renal impairment.
2. Use with caution in patients with raised intracranial pressure or head injury. Bronchospasm may be precipitated in patients suffering from or with a history of bronchial asthma or allergic disease. The possibility of cross-sensitivity with aspirin or other NSAIDs should be considered.
3. Codeine is narcotic analgesic and tolerance, psychological and physical dependence may occur.

4.5 Interaction with other medicinal products and other forms of interaction

Caution should be exercised in patients taking monoamine oxidase inhibitors, thiazide diuretics or oral anticoagulants.

4.6 Pregnancy and lactation

Based on animal studies and clinical experience there is no evidence to suggest foetal abnormalities associated with the use of ibuprofen or codeine. However, as with all drugs, Ibuprofen 200mg / Codeine Phosphate 12.8 mg tablets should be avoided during pregnancy, unless essential. Ibuprofen and codeine are excreted in breast milk.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Side effects including gastrointestinal disturbances occasionally leading to gastrointestinal or peptic ulceration, headache, rash, oedema, blurred vision, hypersensitivity, thrombocytopenia, abnormal liver function and impaired renal function have been reported.

4.9 Overdose

Symptoms of overdosage with ibuprofen could be expected to include the following: headache, vomiting, drowsiness, loss of consciousness and hypotension. Nausea and vomiting are prominent features or codeine overdose. Respiratory depression may also occur with large codeine overdose.

The stomach should be emptied.

Symptoms should be treated on appearance and fluid and electrolyte balance should be monitored and corrected as necessary.

If severe CNS depression has occurred, artificial respiration, oxygen and parenteral naloxone may be needed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ibuprofen is an analgesic which acts peripherally, inhibiting prostaglandin synthesis and the action of chemical mediators of pain. Codeine is a narcotic analgesic acting on central opiate receptors, although its pharmacological effects are thought to be due largely to its biotransformation to morphine.

The combination of a well tolerated peripheral analgesic with a centrally acting analgesic provides optimum pain relief with a lower potential for producing side-effects.

5.2 Pharmacokinetic properties

The elimination half-life of both ibuprofen and codeine is approximately three hours, and both drugs are given three to four times daily. The combination of the two drugs is therefore appropriate from a pharmacokinetic viewpoint; the tablet exhibits normal characteristics for both active substances.

5.3 Preclinical safety data

There are no-preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ibuprofen layer:
Microcrystalline cellulose
Sodium starch glycollate Type A
Hypromellose

Codeine layer:
Microcrystalline cellulose
Pregelatinised maize starch
Povidone

Film coating:
Hypromellose
Talc
Opaspray white M-1-711B
containing: Hypromellose and Titanium Dioxide E171

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Blister packs (250 micrometer PVC/40 gsm PVDC heat sealed to aluminium foil) containing 6, 12 or 24 tablets.

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 Limited
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8 MARKETING AUTHORISATION NUMBER

PA 43/36/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 April 1992

Date of last renewal: 7 April 2002

10 DATE OF REVISION OF THE TEXT

July 2003