Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Diclofenac Sodium 25 mg Tablets Enteric Coated

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 25 mg of diclofenac sodium.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

4.1.1 In the symptomatic management of rheumatoid arthritis including juvenile chronic arthritis, osteoarthritis, ankylosing spondylitis, psoriatic arthropathy, low back pain and acute musculoskeletal disorders including periarthritis, tendinitis, tenosynovitis, bursitis, sprain, strains, dislocations and in acute gout.

4.1.2 In the management of post operative pain and inflammation in orthopaedic dislocations and in acute gout.

4.1.3 In the management of dysmenorrhoea and associated menorrhagia.

4.2 Posology and method of adminstration

Adults: The usual daily dosage is 100mg in divided doses. This may be increased to 150mg daily.

Children: The usual total daily dose is 1 – 3mg/kg daily in divided doses.

Elderly: NSAIDs should be used with particular caution in elderly patients who are more prone to adverse events. The lowest dose compatible with adequate safe clinical control should be employed. See also section 4.4.

Treatment should be reviewed at regular intervals and discontinued if no benefit is seen.

4.3 Contraindications

Use in asthmatic patients hypersensitive (e.g. bronchospasm, rhinitis, urticaria) to aspirin or other non-steroidal anti-inflammatory agents, including diclofenac.

Use in patients with active or suspected peptic ulceration or peptic ulcer disease, or with gastrointestinal bleeding.

4.4 Special warnings and special precautions for use

The product should only be used with great caution in patients with a history of peptic ulcer, gastrointestinal bleeding, hepatic or renal insufficiency, or bleeding diathesis, or intestinal inflammation.

Patients with significant hepatic, renal or cardiac insufficiency should be kept under close surveillance as the use of non-steroidal anti-inflammatory drugs may result in a deterioration in renal function. Assessment of renal function should occur prior to the initiation of therapy and regularly thereafter.

All patients on long term non-steroidal anti-inflammatory treatment should be kept under regular surveillance with monitoring of renal hepatic function, and of haematological parameters. This is particularly important in the elderly. Any evidence of progressive deterioration in function should be regarded as a reason for discontinuing therapy.

Undesirable effects may be reduced by using the minimum effective dose for the shortest possible duration. Patients treated with NSAIDs longterm should undergo regular medical supervision to monitor for adverse events.

As NSAIDs can interfere with platelet function, they should be used with caution in patients with intracranial haemorrhage and bleeding diathesis.

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.

This product is strongly protein bound. Studies to date show no potentiation of oral hypoglycaemics or anticoagulant drugs.

Concurrent use with aspirin results in reduced serum levels of diclofenac sodium and of aspirin and salicylates, although the clinical relevance is unknown.

Co-administration of diclofenac sodium with other systemic non-steroidal anti-inflammatory drugs may increase the risk of unwanted adverse effects.

Diclofenac sodium may increase plasma levels of concurrently administered digoxin or lithium.

The activity of some diuretics (loop type) may be inhibited. The potassium retaining diuretics should be avoided since non-steroidal anti-inflammatory drugs may increase the risk of gastrointestinal haemorrhage. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

Methotrexate: decreased elimination of methotrexate.

Cyclosporin: increased risk of nephrotoxicity with 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.

Anti-hypertensives: reduced anti-hypertensive effect.

Oral hypoglycemic agents: inhibition of metabolism of sulfonylurea drugs prolonged half-life and increased risk of hypoglycaemia.

Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycoside levels.

4.6 Pregnancy and lactation

The product should not be used in pregnancy or lactation unless considered essential by the physician. Use of PG synthetase inhibitors in the third trimester may result in premature closure of the ductus arteriosus. Traces of drug are detectable in breast milk but are not clinically significant.

4.7 Effects on ability to drive and use machines

None Known.

4.8 Undesirable effects

Side effects include gastrointestinal disturbances, headache, dizziness and skin rashes, and less frequently gastric bleeding, fluid retention, hepatitis, renal dysfunction, anaphylaxis, irritability and rarely blood dyscrasias, bronchospasm and erythema multiforme.

4.9 Overdose

As there is no known antidote to diclofenac sodium treatment is symptomatic. Forced emesis should be applied immediately to recover undigested tablets.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A non-steroidal anti-inflammatory agent and inhibitor of PG synthetase.

5.2 Pharmacokinetic properties

The drug is well absorbed with peak plasma levels in 1 – 4 hours. It is extensively metabolised in the liver and excreted through bile and urine. The drug is strongly protein bound. It has a half-life of 2 – 4 hours.

5.3 Preclinical safety data

Not Applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Sodium Starch Glycollate
Polyvidone BP
Maize Starch
Isopropanol
Magnesium Stearate

Sealant:
Hydroxypropylmethyl-cellulose
Stearic Acid
Isopropanol
Purified Water

Enteric Coating:
Eudragit L
Diethylphthalate
Isopropanol
Purified Water
Purified Talc

K-1-3678:
Titanium Dioxide – E 171
Quinoline Yellow Aluminium Lake – E104
Iron Oxide Yellow – E172
Hydroxypropyl Cellulose
Iron Oxide Red – E172
Iron Oxide Black – E 172

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Three years from the date of its manufacture.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Polypropylene tubular container with an open end equipped to accept a polyethylene closure, with a tamper-evident tear strip. Pack sizes are 50, 100, 250, 500 or 1000.

or

Blister packs of 250µ opaque UPVC-PVDC 20µ hard temper aluminium foil- 5-6 gsm vinyl heat seal. The pack sizes are five blister strips, each containing twenty tablets.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Norton Waterford
Unit 301
Waterford Industrial Estate
Waterford

8 MARKETING AUTHORISATION NUMBER

PA 436/9/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th November 1992
Date of last renewal: 27th November 2002

10 DATE OF REVISION OF THE TEXT

August 2003