

PART II

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Ponalgic 250mg hard Capsules.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 250 mg of Mefenamic Acid.

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Hard capsules.

The capsules have a blue cap and yellow body and are printed 'Antigen MA250'.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- 1) For the relief of mild to moderate pain associated with rheumatic muscular or arthritic disorders (including rheumatoid arthritis) trauma, headache, dental pain, post-operative or post-partum states.
- 2) In the management of dysfunctional menorrhagia.
- 3) Primary dysmenorrhoea.

4.2 Posology and method of administration

Route of administration: oral.

Adults only: the usual total daily dose is 1500mg in divided doses.

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

4.3 Contraindications

Use in patients with gastric and/or intestinal ulceration or inflammation.

- 1) Use in pregnancy or lactation.
- 2) Use in patients with renal or hepatic impairment.
- 3) Use in patients shown to be hypersensitive (e.g. bronchospasm, rhinitis, urticaria) to mefenamic acid, aspirin or other non-steroidal anti-inflammatory drugs.
- 4) Use in children.

4.4 Special warnings and precaution for use

Patients on prolonged therapy should be kept under regular surveillance with particular attention to liver dysfunction, rash, blood dyscrasias or development of diarrhoea. Appearance of any these should be regarded as an indication to discontinue therapy immediately.

The product should be used with caution in patients with renal dysfunction and in the elderly.

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

In patients with renal, cardiac or hepatic impairment, caution is required since the use of NSAID's may result in deterioration of renal function. Assessment of renal function should occur prior to the initiation of therapy and regularly thereafter.

Elderly patients are particularly susceptible to the adverse effects of NSAID's. Prolonged use of NSAID's in the elderly is not recommended. Where prolonged therapy is required, patients should be reviewed regularly.

Ponalgic Capsules should be used with caution in patients with a history of peptic ulceration or inflammatory bowel disease.

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

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose- galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration of other plasma protein binding drugs, such as anticoagulants may require adjustment in their dosage.

It is considered unsafe to take NSAID's 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 NSAID's.

Cardiac glycosides: NSAID's may exacerbate cardiac failure, reduced GFR and increase plasma cardiac glycoside levels.

Lithium: decreased elimination of Lithium.

Methotrexate: decreased elimination of methotrexate.

Cyclosporin: increased risk of nephrotoxicity with NSAID's.

Other NSAID's: avoid concomitant use of two or more NSAID's.

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 NSAID's and metabolites.

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

4.6 Pregnancy and lactation

Safety in pregnancy has not been established and mefenamic acid should not be administered during pregnancy. Trace amounts of mefenamic acid may appear in breast milk and mefenamic acid should not be taken by nursing mothers.

4.7 Effects on ability to drive and use of machines:

The ability to drive and use of machines is generally unaffected by mefenamic acid.

4.8 Undesirable effects:

Side effects include diarrhea, rash, renal dysfunction, thrombocytopenia and other blood dyscrasias, bronchospasm, headache, gastrointestinal disturbance.

4.9 Overdose

Symptoms of overdose are variable and may include CNS symptoms such as generalised convulsions. Coma and acute renal failure have been reported with mefenamic acid overdose.

In acute overdosage, the stomach should be emptied by gastric lavage followed by administration of activated charcoal to suppress the absorption of remaining drug. Mefenamic acid is extensively bound to plasma protein, therefore, haemodialysis is of little value. Vital functions should be monitored and intensive supportive therapy applied where necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Mefenamic acid an anthanilic acid derivative, is a non-steroidal agent with anti-inflammatory, analgesic and antipyretic properties. It has been shown to inhibit prostaglandin activity.

5.2 Pharmacokinetic properties:

Mefenamic acid is absorbed from the gastrointestinal tract. Peak plasma concentrations occur about 2 to 4 hours following ingestion. Mefenamic acid is extensively bound to plasma proteins.

About 50% of the dose is excreted in urine, as unchanged drug or metabolites, and approximately 20% may be recovered from faeces. The plasma elimination half life is 2 to 4 hours.

5.3 Preclinical safety data

No further relevant information other than that which is included in other sections of summary of product characteristics

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch
Lactose Monohydrate
Magnesium Stearate
Sodium Starch Glycollate Type A
Sodium Laurilsulfate

Capsule Shell:
Gelatin
Titanium Dioxide E171
Yellow Iron Oxide E172
Erythrosine E127
Indigo Carmine E132
Black Iron Oxide E172

Printing ink:
Shellac
Black Iron Oxide E172
Soya Lecithin
Dimeticone

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 container.

6.5 Nature and contents of container

Polypropylene containers with polypropylene tamper evident caps.
Pack sizes: 50, 100, 500, and 168 capsules.

6.6 Instructions for use and handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Antigen Pharmaceuticals Ltd
Roscrea
Country Tipperary

8. MARKETING AUTHORISATION NUMBER

PA 73/97/1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23rd October 1987/23rd October 2002

10. DATE OF REVISION OF THE TEXT

September 2008