Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Baythrom Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 324 mg acetylsalicylic acid (aspirin), 965 mg citric acid, anhydrous and 1,625 mg sodium hydrogen carbonate. The active ingredients in water become 364 mg sodium acetylsalicylate, 1,296 mg sodium citrate and 209 mg sodium hydrogen carbonate.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Effervescent tablets.
Circular white effervescent tablet with one face flat with bevelled edge and top face embossed to form a rim.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of patients with previous myocardial infarction or with unstable angina pectoris to reduce the risk of death and/or non-fatal myocardial infarction.

4.2 Posology and method of adminstration

Adults
One tablet a day.

Children
Do not give to children and adolescents aged under 16 years, except on medical advice, where the benefit outweighs the risk.

Elderly
The risk/benefit ratio in elderly patients has not been clearly established.
The tablets must always be dissolved in water before taking. They dissolve more quickly in warm water.

4.3 Contraindications

Baythrom should not be administered to patients:

- With a history of hypersensitivity reactions (bronchospasm, rhinitis, urticaria) in response to aspririn, or other salicylates or substances with similar actions e.g. NSAIDs.
- With known hypersensitivity to any of the other ingredients, refer to section 6.1.
- With active peptic ulceration or a history of peptic ulceration.
- With haemorrhagic diseases such as haemophilia.
- Who are pregnant or breast-feeding.
- Receiving doses of methotrexate at 15mg/week or greater.

4.4 Special warnings and special precautions for use

Aspirin may precipitate bronchospasm, and induce allergic or asthmatic reactions, and angioneurotic oedema in susceptible patients.

Undesirable effects may be reduced by using the minimum effective dose for the shortest possible duration. Patients treated with NSAIDs 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 NSAIDs may result in deterioration of renal function. Assessment of the renal function should occur prior to the initiation of therapy and regularly thereafter.

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.

Aspirin may induce gastro-intestinal haemorrhage.

Aspirin should be used with caution in patients:

- With a history of gastrointestinal disorders
- Taking anticoagulants (e.g. coumarin derivatives or heparin)
- Who are hypersensitive to anti-inflammatory or anti-rheumatic drugs

Aspirin can cause gout in patients with low uric acid excretion.

There is a possible association between aspirin and Reye's syndrome given to children. Reye's syndrome is a very rare disease which affects the brain and liver and can be fatal. For this reason aspirin should not be given to children and adolescents under 16 years unless specifically indicated.

As Baythrom contains sodium, caution should be exercised in the treatment of hypertensive patients or if used in patients on a sodium restricted diet.

Due to its inhibitory effect on platelet aggregation, aspirin may cause increased bleeding during and after surgery.

4.5 Interaction with other medicinal products and other forms of interaction

Aspirin may:

- Enhance the effects of anticoagulants, insulin and sulphonylurea hypoglycaemic agents.
- Enhance the activity of methotrexate and increase its toxicity.
- Diminish the effects of uricosuric agents.
- Diminish the effects of diuretics.
- Potentiate the risk of gastro-intestinal bleeding during concomitant therapy with corticosteroids.
- Potentiate the effects and side-effects of other non-steroidal anti-inflammatory drugs.
- Enhance the plasma concentrations of digoxin.
- Enhance the effects of some anti-epileptics, such as sodium valproate and phenytoin.
- Increase the risk of bleeding with thrombolytics and other anti-platelet agents e.g. ticlopidine.

Numerous NSAIDs may interact with antihypertensive medicines although of all NSAIDs, aspirin and sulindac are thought to have the least effect.

Decreased blood salicylate levels may occur when aspirin is taken concomitantly with glucocorticoids. There is a risk of salicylate overdose when glucocorticoids treatment is stopped.

At doses of 3g/day or more, aspirin may:

- Increase risk of ulcers and gastro-intestinal bleeding when taken with other NSAIDs.
- Decrease glomerular filtration when taken with diuretics.
- Decrease glomerular filtration and anti-hypertensive effect when taken with ACE inhibitors.

When taken with alcohol, the effects of aspirin on gastrointestinal tract may increase.

4.6 Pregnancy and lactation

Although clinical and epidemiological evidence suggests the safety of aspirin for use in pregnancy, caution should be exercised when administered to pregnant patients.
Aspirin has the ability to alter platelet function and, therefore, there may be a risk of haemorrhage in infants whose mothers have consumed aspirin during pregnancy. The onset of labour may be delayed and the duration increased, with an increase in maternal blood loss. Therefore, analgesic doses should be avoided during the last trimester.
High doses of aspirin may result in closure of foetal ductus arteriosus *in utero* and possibly persistent pulmonary hypertension in the new born. Kernicterus may be a consequence of jaundice in neonates.
Administration of aspirin at doses greater than 300mg/day, shortly before birth can lead to intra-cranial haemorrhages, particularly in premature babies.
The intake of aspirin by breast-feeding patients should be avoided, as there is a risk of Reye's syndrome. Regular use of high doses could impair platelet function and produce hypoprothrombinaemia in the infant if neonatal vitamin K stores are low.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Gastro-intestinal disorders have been reported for aspirin containing products e.g. nausea, diarrhoea, vomiting and gastro-intestinal bleeding which can lead to anaemia in some cases. Gastro-intestinal ulcers may develop, which may lead to haemorrhaging and perforation.
Rare cases of bronchospasm, asthmatic or hypersensitivity reactions have been reported for aspirin containing products.
Isolated cases of liver function disturbances and severe skin reactions have also been reported.
Due to the effect on platelet aggregation aspirin may be associated with an increased risk of bleeding.
Dizziness and tinnitus have also been reported but these side effects are more commonly indicative of an overdose.
If you experience these or any other unusual effects, stop taking this product and tell your doctor immediately.

4.9 Overdose

Clinical effects
The main features of aspirin overdose are hyperventilation, tinnitus, deafness, vasodilatation and sweating. Coma is uncommon but indicates very severe poisoning.
Treatment
Treatment consists of gastric lavage, forced alkaline diuresis where needed, normalising acid base and electrolyte balance

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The principal basis for the use of aspirin in patients in the proposed indication lies in the ability of aspirin, by inactivating cyclo-oxygenase and thereby blocking the formation of prostaglandin endoperoxides and thromboxane A_2

in platelets, to inhibit aggregation and vessel wall constriction.

5.2 Pharmacokinetic properties

Aspirin is rapidly absorbed from the small intestine after oral ingestion of Baythrom and rapidly distributed to all body tissues. Peak plasma levels occur at approximately 20 minutes. Excretion is mainly renal.

5.3 Preclinical safety data

There are no preclinical safety data of relevance to the prescriber which are additional to those already included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone
Dimeticone
Calcium Silicate
Docusate Sodium
Sodium Benzoate
Saccharin Sodium
Natural and artificial lemon flavour
Natural and artificial lime flavour

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Composite aluminium foil laminate sachets consisting of paper, polyethylene and aluminium foil. Available in pack sizes of 28 tablets.

6.6 Instructions for use and handling

The tablets should not be removed from the foil sachet until immediately before use.
If a foil sachet is damaged and/or the tablets are powdery or discoloured, they should not be used. However, in the event that the tablets are used, they are not harmful.

7 MARKETING AUTHORISATION HOLDER

Bayer plc.,
Bayer House,
Strawberry Hill,
Newbury,
Berkshire,
RG14 1JA,
United Kingdom.

Trading as Bayer plc., Consumer Care Division.

8 MARKETING AUTHORISATION NUMBER

PA 21/38/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th November 1987
Date of last renewal: 23rd November 2004

10 DATE OF REVISION OF THE TEXT

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