

IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0021/057/001

Case No: 2051293

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Bayer PLC

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

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Aspro Clear Effervescent Tablets

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **29/05/2008**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Aspro Clear Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Acetylsalicylic Acid (aspirin) 300.00 mg.
Also contains 150mg (6.5mmol) sodium per tablet.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent Tablet

White, circular tablets, with a scoreline on one face (to allow breaking for ease of swallowing) and the other side plain.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

The symptomatic relief of influenza, feverishness, feverish colds, and of lumbago, sciatica, fibrositis, rheumatic pains, muscular aches and pains.

The relief of mild to moderate pain including headache, migraine, toothache, period pains, sore throat, neuralgia, aches and pains.

4.2 Posology and method of administration

Posology:

Oral.

Tablets must be dissolved in water.

Adults:

2 tablets in half a glass of water every 4 hours as required. Do not exceed 13 tablets in 24 hours unless directed by a doctor. If symptoms persist consult your doctor. Medicines should not be taken in pregnancy without consulting your doctor.

Elderly:

As for adults.

Children:

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

4.3 Contraindications

Aspirin products are contraindicated in patients with active peptic ulceration, haemophilia or who have hypersensitivity to aspirin.

4.4 Special warnings and precautions for use

There is possible association between aspirin and Reye's syndrome when 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 aged under 16 years unless specifically indicated.

4.5 Interaction with other medicinal products and other forms of interaction

Aspirin may enhance the effects of anti-coagulants, and may inhibit the action of uricosuric agents.

4.6 Pregnancy and lactation

There is clinical and epidemiological evidence of safety of aspirin in pregnancy, but it may prolong labour and contribute to maternal and neo-natal bleeding, and so it is best avoided at term. Breast feeding is contraindicated at high doses because of the theoretical risk of affecting clotting mechanisms.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Aspirin may precipitate bronchospasm, and induce asthmatic attacks in susceptible subjects. It may induce gastrointestinal haemorrhage, occasionally major.

4.9 Overdose

Gastric lavage, forced alkaline diuresis and supportive therapy may be employed. Restoration of acid-base balance may be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Absorption of non-ionised aspirin occurs in the stomach and upper intestine.

5.2 Pharmacokinetic properties

Hydrolysis to salicylic acid occurs rapidly in the intestine and in the circulation. Appreciable plasma concentrations are found in less than 30 minutes. After a single dose, a peak value is reached in about 2 hours and then gradually declines. Salicylates are extensively bound to plasma proteins (50-90%); aspirin to a lesser degree. Aspirin and salicylates are rapidly distributed to all body tissues. They appear in milk and cross the placenta.

Aspirin is excreted mainly by the kidneys as salicylic acid and as glucuronide conjugates; also as salicyluric acid and gentisic acid. The biological half life of aspirin after a small single dose is in the region of 4 hours.

5.3 Preclinical safety data

No additional information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol (E421)
Malic acid
Povidone
Docusate sodium
Anhydrous sodium carbonate
Sodium hydrogen carbonate
Saccharin sodium
Citric acid
Lemon flavour

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 package.

6.5 Nature and contents of container

Tablets are packed in aluminium foil/polythene blister strips which are packed into cardboard cartons to contain 18 or 30 tablets.

Not all pack sizes may be marketed.

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

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

8 MARKETING AUTHORISATION NUMBER

PA 21/57/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 June 1976

Date of last renewal: 08 June 2006

10 DATE OF REVISION OF THE TEXT

November 2006