

PIL OF CARDISPRIN ENTERIC COATED TABLETS

13. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Cardisprin 75 mg enteric coated Tablet

13.1 *Strength*

75 mg

13.2 *Pharmaceutical form*

Enteric coated Tablet

14. QUALITATIVE AND QUANTITATIVE COMPOSITION

14.1 *Qualitative declaration*

FLOCEL 101 USP, Partially Pregelatinized starch 1500, Purified Talc BP, Aerosil BP, Tabcoat TC, Acryl-Eze pink

14.2 *Quantitative declaration*

Aspirin BP	75.000
Partially pregelatinized starch 1500	20.000
FLOCEL 101 USP	61.000
Purified talc BP	3.000
Aerosil BP	1.000
Tabcoat TC	4.000
Acryl-Eze pink	21.000

14.3 *Salts and hydrates*

NA

14.4 *Esters and pro-drugs*

NA

14.5 *Oral powders for solution or suspension*

NA

14.6 *Parenterals excluding powders for reconstitution*

NA

14.7 *Powders for reconstitution prior to parenteral administration*

NA

14.8 *Concentrates*

NA

14.9 *Transdermal patches*

NA

14.10 *Multidose solid or semi-solid products*

NA

14.11 *Biological medicinal products*

NA

14.11.1 *Expression of strength*

mg

14.11.2 *The biological origin of the active substance*

NA

14.11.3 *Special provisions for normal immunoglobulins*

NA

14.11.4 Herbal pharmaceutical products

NA

15. PHARMACEUTICAL FORM

Enteric coated Tablets

16. CLINICAL PARTICULARS

16.1 Therapeutic indications

For the secondary prevention of thrombotic cerebrovascular or cardiovascular disease and following by-pass surgery.

16.2 Posology and method of administration

Adults: Patients should seek the advice of a doctor before commencing therapy for the first time

The usual dosage, for long-term use, is 75-150 mg once daily. In some circumstances a higher dose may be appropriate, especially in the short term, and up to 300mg a day may be used on the advice of a doctor.

Antithrombotic action: 150mg at diagnosis and 75mg daily thereafter.

16.3 Method of administration

Oral.

16.4 Contraindications

Hypoprothrombinaemia, haemophilia and other bleeding disorders.

Active peptic ulceration or a history of peptic ulceration.

Hypersensitivity to the active substance (aspirin) or to any of the excipients.

16.5 Special warnings and precautions for use

There is a 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 aged under 16 years unless specifically indicated (c.g. for Kawasaki's disease). Before commencing long-term aspirin therapy for the management of cardiovascular or cerebrovascular disease patients should consult their doctor who can advise on the relative benefits versus the risks for the individual patient. Aspirin decreases platelet adhesiveness and increases bleeding time. Haematological and haemorrhagic effects can occur, and may be severe. Patients should report any unusual bleeding symptoms to their physician. Care is advised when stopping antiplatelet therapy after stent insertion either after a fixed period of time or in preparation for a planned surgical procedure, as the balance between stent thrombosis and excessive bleeding has to be carefully assessed. Salicylates should be used with caution in patients with a history of peptic ulceration or coagulation abnormalities. They may also induce gastro-intestinal haemorrhage, occasionally major. They may also precipitate bronchospasm, urticaria or acute rhinitis or induce attacks of asthma in susceptible subjects. Aspirin should be used with caution in patients with impaired hepatic or renal function (avoid if severe), or in patients who are dehydrated.

Patients with hypertension should be carefully monitored. Cardisprin 75mg EC Tablets can increase the risk of bleeding after some surgical interventions such as dental surgery. This medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

16.6 Paediatric population

NA