SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF MEDICINAL PRODUCT
COROSAN 75 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains 75 mg of dipyridamole.
Excipients with known effect: lactose
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Tablets.

4. CLINICAL INFORMATION

4.1 Therapeutic indications
Corosan is indicated:
- As an adjunct to oral anticoagulation for prophylaxis of thromboembolism associated with prosthetic heart valves.
- As an alternative to exercise stress in thallium myocardial imaging particularly in patients unable to exercise or in those for whom exercise may be contraindicated.

4.2 Posology and method of administration
Posology
4-6 capsules per day in divided doses.

Method of administration
The medicine must be ingested on an empty stomach one hour before meals.

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Acute heart attack.

4.4 Special warnings and precautions for use
The medicine should be used with caution in hypotensive patients because excessive doses can induce peripheral vasodilatation.
This product contains lactose. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction
Interferences may occur with anticoagulant treatments: check the blood coagulation parameters carefully.

4.6 Fertility, pregnancy and lactation
No toxic effects for mother and child following the use of dipyridamole during pregnancy are found in the literature.

4.7 Effects on ability to drive and operate machinery
COROSAN does not affect your ability to drive or operate machinery.

4.8 Undesirable effects
The following side effects are possible and are listed by frequency:

Very common (may affect more than 1in 10 patients)
headache, dizziness, diarrhoea, nausea.

Common (may affect up to 1 in 10 patients)
angina pectoris (chest pain), vomiting, rash (when spots or injuries of various types appear on the skin), myalgia (pain in the muscles).

Not known (frequency cannot be estimated from the available data)
thrombocytopenia (reduction in the number of blood platelets), hypersensitivity (allergy), angioedema (urticarial-like condition which occurs with swelling of the skin and mucous membranes), tachycardia (increased heart rate), hypotension (low blood pressure), flushing, bronchospasm (narrowing of the bronchi which causes severe breathing difficulty due to reduced air passage), hives, haemorrhage (severe bleeding) during or after surgery. A worsening of the symptoms of coronary arteries disease and the presence of dipyridamole in gallstones have been observed.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il.

4.9 Overdose
In case of ingestion of excessive doses of dipyridamole, digestive disorders and headaches were observed that disappear quickly.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: platelet aggregation inhibitors excluding heparin.
ATC code: B01AC07
Dipyridamole greatly increases coronary blood flow without causing changes in rhythm and without affecting the central nervous system. In this case, the oxygen supply to the myocardium and cardiac performance improve. Dipyridamole has strong antiplatelet activity and is therefore effective in diseases related to risk of cardiac, cerebral and renal thrombosis.

5.2 Pharmacokinetic properties
Absorption: dipyridamole administered orally is absorbed in the proximal part of the small intestine.
Distribution: the maximum plasma concentration occurs after about 2 hours after administration.
Elimination: dipyridamole is metabolized in the liver and excreted as monoglucuronide almost exclusively via the bile; elimination by the kidneys is negligible.

5.3 Preclinical safety data
TOXICOLOGY: the LD_{50} evaluated in rat after oral administration amounted to 6 g/kg. Dipyridamole has not been shown to have teratogenic effects leading to a rise in carcinogenesis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Maize starch, lactose monohydrate, talc, magnesium stearate.

6.2 Incompatibilities
None known.

6.3 Shelf life
The expiry date of the product is indicated on the packaging material.

6.4 Special precautions for storage
Store below 25^0C.

6.5 Nature and contents of container
Aluminium/PVC/PVDC of 30 tablets (3 blister packs of 10 tablets).

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MANUFACTURER
LABORATORIO FARMACOLOGICO MILANESE S.r.l., Via Monterosso
Caronno Pertusella, Italy.

8. MARKETING AUTHORISATION HOLDER
RAZ PHARMACEUTICS LTD., 6 Hamatechet st., Kadima, Israel.

9. MARKETING AUTHORISATION NUMBER
167-53-35927-00

Approved in June 2021

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