

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

This medicine is to be supplied with doctor's prescription only

COROSAN 75 mg tablets

Active ingredient:

Each tablet contains Dipyridamole 75mg.

For the list of inactive ingredients - see section 6, "Additional information" in this leaflet.

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains essential information about this medicine. If you have any further questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. Do not pass it to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

- 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.

Therapeutic group: platelet aggregation inhibitors excluding heparin.

2. Before using this medicine:

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient Dipyridamole or to any of the other ingredients that this medicine contains (see section 6, "Additional information").
- you suffer from serious heart problems (acute heart attack).

Special warnings regarding the use of the medicine:

Talk to your doctor or pharmacist before taking COROSAN.

Take COROSAN with caution if you suffer from low blood pressure (hypotension), since excessive doses may cause dilation in the small arteries and veins (peripheral vasodilation) with consequent excessive drop in blood pressure.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, inform your doctor or pharmacist.

Especially if you are taking COROSAN together with other medicines used to prevent coagulation (anticoagulants), in this case, it is advised to undergo a blood test to check your coagulation parameters.

Drug use and food

Take the medicine on an empty stomach, one hour before meals.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to get pregnant, consult your doctor or pharmacist before taking this medicine.

In the literature, there are no data of toxic effects for the mother and the foetus from the use of dipyridamole in pregnant women.

Driving and using machines:

COROSAN does not influence the ability to drive or use machinery.

Important information on some of the drug ingredients:

COROSAN contains lactose monohydrate -Lactose is a sugar. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicinal product.

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. You should check with the doctor or the pharmacist if you are unsure about the drug dosage and treatment regimen.

The Dosage treatment regimen will be determined by the doctor only.

The usual recommended dose is 4-6 tablets per day, taken in separate doses.

Do not exceed the recommended dose.

Treatment duration - Your doctor will instruct you regarding the duration of the treatment.

How to take the medicine - The drug should be taken orally with water, on an empty stomach, one hour before meals.

To facilitate swallowing, it is possible, if necessary, to cut the tablet for immediate use. Swallow the two parts together immediately after cutting it.

If you have accidentally taken a higher dose

You may suffer from stomach or intestine disorders (gastrointestinal tract) and headache, which will disappear quickly.

If you have accidentally taken an overdose or if a child has accidentally swallowed the medicine, immediately contact a doctor or go to a hospital emergency room and take the medicine package with you.

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor. If you have any doubts about the use of this medicine, contact your doctor or pharmacist.

Adhere to the treatment as recommended by the doctor.

If you stop taking the medicine

Even if your medical condition has improved, do not stop the drug treatment without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult the doctor or the pharmacist.

4. Side effects

Like any medicine, the use of COROSAN 75mg may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

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

Very common (may affect more than 1 in 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 dipyrindamole in gallstones have been observed.

If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult a doctor.

Reporting of side effects

You can report side effects to the Ministry of Health by clicking the "report side effects due to medication" in the homepage of the Ministry of Health (www.health.gov.il) referring to an online form for reporting side effects, or by clicking the link: <https://sideeffects.health.gov.il> .

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the outer package. The expiry date refers to the last day of that month.
- Store below 25°C.

- Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient the medicine also contains: maize starch, lactose monohydrate, talc, magnesium stearate.

What does the medicine look like and what is the content of the package:

COROSAN is in the form of tablets 75 mg.

Each pack contains 30 tablets in blister (3 blisters of 10 tablets).

Manufacturer:

Laboratorio Farmacologico Milanese S.r.l., Via Monterosso, Caronno Pertusella, Italy

Marketing Authorization Holder:

RAZ Pharmaceuticals Ltd., 6 Hamatechet St., Kadima, Israel.

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