

PACKAGE LEAFLET: Information for the user

KORONARINE

Sugar-coated tablets – 25 mg

(Dipyridamole)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further question, ask your doctor or pharmacist.
- This medication has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What Koronarine is and what it is used for
2. Before you take Koronarine
3. How to take Koronarine
4. Possible side effects
5. How to store Koronarine
6. Further information

1. WHAT KORONARINE IS AND WHAT IT IS USED FOR

Koronarine contains dipyridamole as active substance. Dipyridamole prolongs the abnormally decreased survival time of platelets. It is an inhibitor of the platelets aggregation, although the mechanism of action has not been fully clarified.

The mechanism of action is related to:

- 1) adenosine reuptake inhibition from erythrocytes, which in turn is an inhibitor of the platelet reactivity;
- 2) inhibition of phosphodiesterase, which leads to the increased cyclic adenosine - 3', 5' monophosphate in platelets and

3) inhibition of thromboxane A2, which is a powerful stimulant of platelet activation.

Koronarine 25 mg sugar-coated tablets are used as adjunct during treatment with anticoagulants taken by mouth (coumarin anticoagulants) for the prophylaxis of thromboembolic complications from prosthetic heart valves. Alone or in combination with aspirin it is indicated also for the prevention of myocardial infarction and to reduce mortality from myocardial infarction.

2. BEFORE YOU TAKE KORONARINE

Do not take Koronarine:

- if you are hypersensitive (allergic) to dipyridamole or to any of the excipients of Koronarine.

If you think you have any of the situations mentioned above, do not take it, talk to your doctor first and follow the given advice.

Warning and precautions

Tell your doctor if:

- you have rapid worsening angina;
- you have subvalvular aortic stenosis or;
- you are hemodynamically unstable in the period after the attack has passed;
- you have coagulation disorders;
- you have hypotension;
- you suffer from heart failure;
- you suffer from myasthenia gravis;
- you use simultaneously drugs that increase the risk of bleeding;
- you have migraine, because it may worsen;
- the patient is a child under 12 years old because safety and efficacy of dipyridamole in this age have not yet been determined.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription, such as:

- drugs containing methylxanthines derivatives (anti-asthmatic preparations with theophylline or aminophylline) since they may reduce the effect of dipyridamole and should not be used simultaneously;
- drugs that widen blood vessels (vasodilators), because dipyridamole can enhance the antihypertensive effect;
- antacids, dipyridamole efficacy may be reduced when it is taken concomitantly with antacids so their concomitant use should be avoided;
- antiarrhythmics (adenosine), dipyridamole increases the exposure to antiarrhythmics.

These drugs may be affected by dipyridamole, or may affect the way it acts. Therefore during concomitant use, dosage of dipyridamole may be needed to be reduced or increased. Your doctor or pharmacist will advise you.

Taking Koronarine with food and drinks

It is recommended that the drug be taken before meals and drinking alcohol is not recommended during the period of taking the drug.

Pregnancy

Tell your doctor or pharmacist if you are pregnant or are planning to have a baby. Dipyridamole should not be used in the first trimester of pregnancy, while in the rest of this period, it should be used with caution and only if the therapeutic benefits for the mother outweigh the possible risk to the fetus.

Breastfeeding

Tell your doctor or pharmacist if you are breastfeeding. Dipyridamole passes into breast milk. Your doctor or pharmacist will discuss about the risks and benefits of taking it if you are breastfeeding or are planning to breastfeed your baby.

Driving and using machines

Be careful when driving or operating machinery since Koronarine may cause dizziness, fatigue or blurred vision.

Important information about some of the excipients of Koronarine

This medicinal product contains lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine also contains sodium benzoate and the azo dye Sunset Yellow FCF (E 110), which may cause allergic reactions.

3. HOW TO TAKE KORONARINE

Always take Koronarine only as your doctor has told you. If you feel that the effects of Koronarine are too strong or too weak, talk to your doctor or pharmacist.

The drug should be taken one hour before meals with a glass of water.

It is recommended that the tablets should be taken at the same time every day.

Dosage regimen of Koronarine is as follows:

Adults and the elderly: The normal daily dose is 75-100 mg daily, in 3 to 4 divided doses.

Children: The normal daily dose is 5 mg/kg bodyweight, in divided doses.

Your doctor may ask you to take Koronarine for a longer time. Ask your doctor for advice if you are not sure for how long it should be taken.

If you take more Koronarine

If you take more Koronarine than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

If you forget to take Koronarine

If you forget to take one dose, take the next dose in its usual time.

Do not take a double dose to make up a forgotten dose.

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

All medicines may cause side effects. Sometimes they are serious, most of the time they are not.

Do not get alarmed by this list of possible side effects. You may not get any of them. The side effects after therapeutic doses are usually minimal and transient. During long-term use, the initial side effects usually disappear.

Tell your doctor if any of the following side effects concerns you:

Very common (may affect more than 1 in 10 people):

- since dipirydamole has vasodilator effects, it can cause headache, which usually disappears after dose reduction;
- dizziness;
- feeling sick;
- mild diarrhea.

Common (may affect up to 1 in 10 people):

- fainting;
- hypotension;
- facial flushing;
- dyspepsia;
- muscle pain;
- worsening of the symptoms of heart disease such as chest pain and shortness of breath;
- vomiting;
- exanthema.

Not known (frequency cannot be estimated from the available data):

- thrombocytopenia that may cause prolonged bleeding (haemorrhage) from bruising, including during or after surgery;
- increased resting heart rate (tachycardia);

- bronchospasm;
- angioedema;
- hypersensitivity reaction.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE KORONARINE

Keep this medicine out of the sight and reach of children.

Do not use Koronarine after the expiry date which is stated on the pack.

Do not store above 25°C!

Keep this medicine in the original package.

6. FURTHER INFORMATION

What Koronarine contains

The active substance is dipyridamole.

Each sugar-coated tablet contains 25 mg dipyridamole.

The excipients are: maize starch, lactose monohydrate, gelatin, talc, magnesium stearate, microcrystalline cellulose, povidone, calcium carbonate, titanium dioxide, sucrose, yellow iron oxide, red iron oxide, Sunset Yellow FCF (E 110), sodium benzoate, shellac, carnauba wax, beeswax white.

Contents of the pack

Box with 60 sugar-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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