

Package leaflet: Information for the patient

Pyranistole 200 mg Prolonged-release Capsules

Dipyridamole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Pyranistole Capsules are and what they are used for

The name of your medicine is Pyranistole Capsules. It contains a medicine called dipyridamole. This belongs to a group of medicines called 'anti-thrombotic agents', which are used to help stop blood clots forming.

Pyranistole Capsules are used:

- To help stop blood clots which may occur if you have had your heart valves replaced.
- In people who have had a stroke caused by a blood clot in the brain. This medicine reduces the risk of having another stroke.

2. What you need to know before you take Pyranistole capsules

Do not take Pyranistole Capsules:

- if you are allergic to dipyridamole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Pyranistole Capsules if:

- You have angina or other heart problems (including heart valve or circulation problems) or have had a recent heart attack
- You have myasthenia gravis (a rare muscle problem)
- You have any bleeding problems
- You are pregnant or planning to become pregnant or are breast-feeding.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

Children and adolescents

Dipyridamole should not be given to children.

Other medicines and Pyranistole Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription or herbal medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines for high blood pressure
- Medicines for muscle weakness such as something called a ‘cholinesterase inhibitor’
- Aspirin (or planning to take aspirin for any condition)
- Adenosine injection - used for heart problems or tests on the heart
- Warfarin or other medicines to stop blood clots forming. If so, tell them at your next visit to the anticoagulant clinic that you are now taking dipyridamole.

If you are having heart tests

This medicine contains dipyridamole. Dipyridamole is also sometimes given as an injection during tests to see if the heart is working properly (also called ‘myocardial imaging’). This means that the test and your medicine may contain the same substance. If you are going to have an injection of dipyridamole, tell the doctor that you are taking Pyranistole Capsules.

Pyranistole Capsules with alcohol

Do not take this medicine with alcohol because the risk of side effects may be increased.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Dipyridamole should only be used during breast-feeding if your doctor thinks it is necessary.

Driving and using machines

You may feel dizzy while taking this medicine. If this happens do not drive or use any tools or machines.

3. How to take Pyranistole Capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

- One capsule twice a day
- Usually one in the morning and one in the evening
- It is best to take it with food
- Swallow the capsule whole
- Do not crush or chew it.

Use in children and adolescents

This medicine is not recommended for children.

If you take more Pyranistole Capsules than you should

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you, even if there are no capsules left.

If you forget to take Pyranistole Capsules

- If you forget a dose, take it as soon as you remember it
- However, if it is time for the next dose, skip the missed dose
- Do not take a double dose to make up for a forgotten capsule.

If you stop taking Pyranistole Capsules

Do not stop taking this medicine until you have spoken to your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions

If you have an allergic reaction, stop taking your medicine and see a doctor straight away. The signs may include feeling breathless, runny nose, severe rash with itching, swelling and swelling around the eyes.

Other side effects that have been reported are described below. They are listed as either very common, common, or not known.

Very common (affects more than 1 in 10 people)

- Headache
- Feeling dizzy
- Feeling sick (nausea)
- Diarrhoea

Common (affects less than 1 in 10 people but more than 1 in 100 people)

- Muscle pain
- Being sick (vomiting)
- Worsening of the symptoms of heart disease such as chest pain and shortness of breath

Not Known

- Hot flushes
- Lowering of blood pressure or increased heart rate
- A blood problem called 'thrombocytopenia' which can cause bruising and prolonged bleeding from wounds, including during or after surgery

In people who have gallstones, the dipyridamole in this medicine can be absorbed into the gallstones.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pyranistole Capsules

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

Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

Do not throw away 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. Contents of the pack and other information

What Pyranistole Capsules contains

The active substance is dipyridamole. Each capsule contains 200mg of dipyridamole.

The other ingredients are tartaric acid, povidone, co-povidone, talc, isopropyl alcohol, hypromellose, simeticone emulsion, butylated methacrylate copolymer, hypromellose phthalate, stearic acid, triacetin and acetone.

The capsule shell contains gelatin and titanium dioxide (E171).

The ink printed on the capsule shell contains shellac, propylene glycol, black iron oxide (E172) and potassium hydroxide.

What Pyranistole Capsules look like and contents of the pack

Each prolonged-release capsule contains yellow coloured pellets encapsulated in opaque, white hard gelatin capsule shells (approximately 23 mm x 8 mm). Each capsule is imprinted with “RENATA” on the cap and “DPY 200” on the body with edible black ink.

Each 30 capsule bottle also contains 1 silica gel bag and a molecular sieve bag to protect the capsules from moisture. Do not eat or swallow.

Each 60 capsule bottle also contains 2 silica gel bags and a molecular sieve bag to protect the capsules from moisture. Do not eat or swallow.

Pyranistole Capsules are available in bottles containing 30 or 60 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Renata Pharmaceuticals (Ireland) Limited
13 – 18 City Quay,
Dublin 2,
Ireland

Distributed by:

Azure Pharmaceuticals Ltd
Blackrock,
Co. Louth
Ireland

Manufacturer:

Alterno Labs d.o.o.
Brnčičeva ulica 29,
Ljubljana-Črnuče, 1231, Slovenia

Or

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