

Package leaflet: Information for the patient

Perazodin 25 mg coated tablets
Perazodin 75 mg coated tablets
Perazodin 100 mg coated tablets

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

1. What Perazodin is and what it is used for
2. What you need to know before you take Perazodin
3. How to take Perazodin
4. Possible side effects
5. How to store Perazodin
6. Contents of the pack and other information

1. What Perazodin is and what it is used for

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

Perazodin helps stop blood clots which may occur if you have had your heart valves replaced.

2. What you need to know before you take Perazodin

Do not take Perazodin

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Perazodin 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.
- you have been told by your doctor that you have an intolerance to some sugars.

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

Other medicines and Perazodin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Perazodin can affect the way some other medicines work. Also some other medicines can affect the way Perazodin works.

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’.
- antacids - for indigestion.
- 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 Perazodin.

If you are having heart tests:

Perazodin 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 Perazodin.

Pregnancy, breast-feeding and fertility

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.

Tell your doctor or pharmacist if you are breast-feeding as Perazodin should only be used during breast-feeding if your doctor considers it essential.

Driving and using machines

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

Excipient warnings

Perazodin 25 mg, 75 mg and 100 mg coated tablets contain 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 medicinal product.

Perazodin 25 mg, 75 mg and 100 mg coated tablets contain sodium.

This medicine contains less than 1 mmol sodium (23 g) per dose (maximum daily dose), that is to say essentially ‘sodium-free’.

Perazodin 25 mg and 75 mg coated tablets contain Ponceau 4R, cochineal Red A (E124).

May cause allergic reactions.

Perazodin 25 mg coated tablets contain Sunset yellow FCF (E110).

May cause allergic reactions.

3. How to take Perazodin

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

The recommended dose is between a total of 300 and 600 mg each day.

- This is taken in three or four separate doses.
- The most you can take in a day is 600 mg.
- It is best to take the tablets before meals.
- Swallow the tablets whole.
- Do not crush or chew the tablets.

Use in children

Perazodin is not recommended in children.

If you take more Perazodin 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 tablets left.

If you forget to take Perazodin

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 dose.

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 for Perazodin are described below. They are listed as either very common, common, or not known.

Very common: may affect more than 1 in 10 people

- headache.
- feeling dizzy.
- feeling sick (nausea).
- diarrhoea.

Common: may affect up to 1 in 10 people:

- muscle pain.
- being sick (vomiting).
- worsening of the symptoms of heart disease such as chest pain and shortness of breath.

Not known: frequency cannot be estimated from the available data

- hot flushes.
- lowering of blood pressure.
- 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 the national reporting system (see details below).

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

Malta

ADR Reporting Website:

www.medicinesauthority.gov.mt/adrportal

5. How to store Perazodin

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 label or carton after ‘EXP’. The expiry date refers to the last day of that month.

Store below 25 °C. Protect from light and moisture.

6. Contents of the pack and other information

What Perazodin contains

- The active substance is dipyridamole.

Perazodin 25 mg coated tablets: Each coated tablet contains 25 mg dipyridamole.

Perazodin 75 mg coated tablets: Each coated tablet contains 75 mg dipyridamole.

Perazodin 100 mg coated tablets: Each coated tablet contains 100 mg dipyridamole.

- The other ingredients are:

Perazodin 25 mg coated tablets: lactose monohydrate, povidone, cellulose microcrystalline, sodium starch glycolate (Type A), silica colloidal anhydrous, magnesium

stearate, talc, hypromellose, macrogol 400, titanium dioxide, talc, gelatin, macrogol 6000, sucrose, calcium carbonate, sunset yellow FCF aluminium lake E110, ponceau 4R cochineal red A E124.

Perazodin 75 mg coated tablets: lactose monohydrate, povidone, cellulose microcrystalline, sodium starch glycolate (type A), silica colloidal anhydrous, magnesium stearate, talc, hypromellose, macrogol 400, titanium dioxide, talc, gelatin, macrogol 6000, sucrose, calcium carbonate, ponceau 4R cochineal red A E124, quinolone yellow E104.

Perazodin 100 mg coated tablets: lactose monohydrate, povidone, cellulose microcrystalline, sodium starch glycolate (type A), silica colloidal anhydrous, magnesium stearate, talc, hypromellose, macrogol 400, titanium dioxide, talc, gelatin, macrogol 6000, sucrose, calcium carbonate.

What Perazodin looks like and contents of the pack

Perazodin 25 mg coated tablets: light orange, round, coated tablets.

Perazodin 75 mg coated tablets: orange, round, coated tablets.

Perazodin 100 mg coated tablets: white, round, coated tablets.

Pack sizes:

Perazodin 25 mg coated tablets:

PVC/Aluminium blisters. Pack sizes of 100 and 1000 coated tablets.

PP containers with PE closure. Pack size of 1000 coated tablets.

Perazodin 75 mg coated tablets:

PVC/Aluminium blisters. Pack sizes of 20, 100 and 1000 coated tablets.

PP/PE containers. Pack size of 30 coated tablets.

Perazodin 100 mg coated tablets:

PVC/Aluminium blisters. Pack sizes of 30, 100 and 1000 coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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