

PACKAGE LEAFLET: INFORMATION FOR THE USER

Persantin

75 mg coated tablets

DIPYRIDAMOLE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

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

1. WHAT PERSANTIN IS AND WHAT IT IS USED FOR

Persantin contains the active ingredient dipyridamole, which belongs to the group of medicines called antiplatelet medicines (medicines that help prevent the formation of blood clots by preventing the accumulation of platelets). It is used as an adjunct to oral anticoagulants for the prevention of thromboembolism associated with implantation of artificial heart valves.

2. BEFORE YOU TAKE PERSANTIN

Do not take Persantin:

- If you are allergic to the active substance or any of the other ingredients (listed in section 6).

Warnings and precautions

Check with your doctor before taking this medicine:

- If you suffer from severe damage to the blood vessels of the heart (including unstable angina and recent heart attack, blockage of blood flow from the left ventricle or heart failure)
- If you have myasthenia gravis (a rare disease that affects muscles)

- If you are pregnant, planning to become pregnant, or are breast• feeding.

Children

There are limited data on the use of Persantina in children. The medicine is not intended for use in children.

Persantin and other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

It is necessary to notify your doctor if you are taking any of the following medicines:

- adenosine (medicine used to treat heart problems). Persantin increases the level of adenosine in the blood and its effect on the heart and blood vessels. Your doctor will consider adjusting the dose of adenosine.
- medicine for thinning the blood/prevent blood clots (including acetylsalicylic acid).
- medicines for the treatment of high blood pressure. Persantin can boost their effect on reducing blood pressure.
- medicines for the treatment of muscle weakness also called cholinesterase inhibitors. Persantin may reduce the effect of these medicines.
- Theophylline and related medicines called xanthine. These medicines may decrease the effect of Persantin.

Pregnancy, breastfeeding and fertility

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

There is no relevant information on the safety of Persantin in pregnancy. Non• clinical studies have shown no increased risk.

Still, the medicine should not be used in pregnancy, especially in the first three months, unless the expected benefit to the mother is more important than the possible risk to the fetus.

Persantin can be used during lactation only if your doctor deems it necessary.

No studies were conducted on the effect of Persantin on the fertility of men.

Driving and using machines

When taking this medicine you may experience dizziness. It is therefore recommended caution when driving or using machines. If you experience dizziness, do not drive or use machines.

Persantin contains sucrose and sunset yellow (E110)

This medicine contains sucrose. If your doctor has told you that you have intolerance to some sugars, before you start taking this medicine consult with your doctor.

This medicine contains the color sunset yellow (E110), and it may cause allergic• type reactions.

3. HOW TO TAKE PERSANTIN

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

The recommended dose is between 300• 450 mg daily, divided into more doses. The maximum permitted daily dose is 600 mg.

Use in children

There are only limited data on the use of Persantin in children. The medicine is not intended for use in children.

If you take more than you should

Contact your doctor immediately or go to the nearest hospital for advice. Bring the packaging of the medicinal product even if there is no tablet inside.

If you forget to take Persantin

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

If you stop taking Persantin

Contact your doctor before you stop taking Persantin.

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

4. POSSIBLE SIDE EFFECTS

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

In the case of the occurrence of any of the following signs of an allergic reaction, stop taking Persantin, and seek medical aid:

- difficulties in breathing, with or without swelling of the face, lips, tongue and/or throat,
- swelling of the face, lips, tongue and/or throat can make it difficult to swallow,
- rash accompanied by itching of the skin.

Other side effects that have been reported with Persantina are described below.

Very common (affects more than 1 in 10 patients taking the medicine)

Common (affects 1 in 10 to 1 in 100 patients who take the medicine)

Uncommon (affects 1 in 100 to 1 in 1000 patients taking the medicine)

Rare (affects up to 1 in 1000 to 1 in 10,000 patients who take the medicine)

Very rare (affects less than 1 in 10,000 patients who take the medicine)

It is not known (frequency cannot be determined from the available data).

Very common side effects

- headache, dizziness
- diarrhea, nausea

Common side effects

- angina pectoris
- vomiting
- skin rash
- muscle pain.

Side effects of an unknown frequency

- a reduced number of platelets (blood platelets)
- sensitivity, angioedema
- an accelerated heart rate
- decreased blood pressure, hot flushes
- narrowing of the Airways
- the hives
- bleeding after the surgery, bleeding during the procedure.

In people who have gallstones, dipyridamole from of the medicine can be absorbed into the gallstones.

Reporting of side effects:

If you notice any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE PERSANTIN

Keep out of the reach and sight of children. Store at a temperature up to 25 ° c.
Persantin must not be used after the expiry date which is stated on the carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to preserve the environment.

6. FURTHER INFORMATION**What Persantin contains**

1 coated tablet contains 75 mg of dipyridamole.

Excipients: calcium phosphate dibasic, anhydrous; maize starch, dried; corn starch, soluble; silicon dioxide; magnesium stearate; sucrose; TALC; Arabian gum; titanium dioxide (E171); MACROGOL 6000; karnaubawax; beeswax, white; Yellow Yellow Orange S (85 percent) (E110); purified water; ethanol, anhydrous.

Contents of the Pack

60• coated tablets in PVC/PVDC blister, in a box

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer of the medicinal product

Delpharm Reims
10 rue Colonel Charbonneaux, Reims, 51100
France