

New Zealand Consumer Medicine Information

PERSANTIN[®] PL 150 mg Sustained-release capsules **PERSANTIN[®] 25 mg tablets** *Dipyridamole*

This leaflet answers some common questions about PERSANTIN. It does not contain all available information.

It does not take the place of talking to your doctor or pharmacist. Keep this information with your tablets. You may need to read it again later.

To find out more about PERSANTIN

You should ask your doctor or pharmacist if you have any questions about your medicine or if you have any concerns about taking PERSANTIN.

What PERSANTIN is used for

PERSANTIN used in combination with other medicines helps to prevent blood clots in patients with prosthetic heart valves. The ability of PERSANTIN to prevent blood clots is due to its effect on blood cells known as platelets. If you want more information, ask your doctor or pharmacist.

Before taking PERSANTIN

When not to take PERSANTIN

Only take PERSANTIN if it has been prescribed for you by a doctor. Never give it to someone else even if their symptoms seem to be the same as yours.

Do not take PERSANTIN if you are allergic to it or to any of the ingredients. These ingredients are listed in full at the end of this leaflet. If you are uncertain as to whether you have such an allergy you should raise this concern with your doctor. You should never take PERSANTIN after the EXPIRY DATE on the pack.

Before you start taking PERSANTIN

It is essential that your doctor knows your medical history before prescribing PERSANTIN. Before taking PERSANTIN, you must tell your doctor if you have, or have had, any of the following conditions:

- any heart condition (e.g. angina, heart attack or heart failure, heart valve problems)
- severe muscle disease (myasthenia gravis)
- gallstones

If you are uncertain as to whether you have, or have had, any of these conditions you should raise those concerns with your doctor.

Before taking PERSANTIN you must tell your doctor if you are taking any other medicines, obtained with or without a doctor's prescription. In particular you must tell your doctor if you are taking:

- aspirin
- warfarin or any other agent that affects the ability of the blood to clot (these agents are known as anticoagulants)
- any medicine for the treatment of high blood pressure
- neostigmine, distigmine and related medicines (used, for example, in the treatment of myasthenia gravis)
- adenosine, used for heart rhythm disorders

Special care is required when PERSANTIN is used with aspirin or an anticoagulant such as warfarin.

PERSANTIN 25 mg tablets contains 13 mg sucrose and 25 mg lactose monohydrate, resulting in 312 mg sucrose and 600 mg lactose monohydrate per maximum recommended daily dose for adults. Patients with the rare hereditary conditions of fructose intolerance or galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. PERSANTIN 25 mg tablets also contain sunset yellow (E 110), which may cause allergic reactions.

Pregnancy

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication. Special care is recommended during pregnancy, particularly in the first three months.

Breastfeeding

Ask for your doctor's advice if you are breastfeeding or likely to breastfeed during the course of your medication. Special care is recommended if you are breastfeeding as the active ingredient has been reported to distribute into breast milk.

Children

There is limited information about the use of PERSANTIN in children.

Taking PERSANTIN

Recommended dose for the 25 mg tablets

The recommended dose for adults is three to four tablets four times a day one hour before meals (taken at regular intervals). If your doctor has prescribed a different dose, you should ask for further information from your doctor or pharmacist.

Recommended dose for the 150 mg capsules

The recommended dose for adults is two to three capsules a day. The medicine is usually taken in the morning and in the evening, and preferably with meals. The capsule should be swallowed whole without chewing.

Discuss with your doctor how long you will need to take this medicine.

If your doctor has prescribed a different dose, you should ask for further information from your doctor or pharmacist.

PERSANTIN helps control your condition, but does not cure it. Therefore you must take

PERSANTIN every day. Continue taking your medicine for as long as your doctor tells you to.

If you forget to take a dose

It is important to take PERSANTIN as directed. If you miss a dose, take it as soon as you remember. However, if you remember when it is almost time for your next dose, take only your usual dose at that time. Do not take a double dose to make up for the dose that you missed.

Overdose

Contact your doctor, pharmacist or Poisons Information Centre (telephone 0800 764 766) immediately if you think that you or anyone else may have taken too much PERSANTIN.

Signs of overdose may include feeling warm, flushing, sweating, restlessness, weakness and dizziness. There may be effects on the heart and circulation causing chest pain, an increase in pulse rate and a drop in blood pressure.

Effects on Ability to Drive or Operate Machinery

Caution is recommended when driving a car or operating machinery. If you experience dizziness you should avoid potentially hazardous tasks such as driving or operating machinery.

While you are taking PERSANTIN

Tell your doctor or pharmacist if you begin taking any other medicine while you are taking PERSANTIN. This applies to all medicines obtained with or without a doctor's prescription.

If you plan to have 'pharmacological stress testing', make sure you tell your doctor that you are taking PERSANTIN.

Side effects

You should be aware that all prescription medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing. Your doctor has weighed the risks of you taking PERSANTIN against the benefits they expect it will have for you.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

If side effects occur, they are usually mild and transient when PERSANTIN is used at the recommended dose. In most cases side effects reduce or disappear as treatment is continued. The following side effects have been reported with PERSANTIN:

- Headache, dizziness
- Stomach upset, diarrhoea, nausea, vomiting
- Muscle aches and pains
- Hot flushes
- Low blood pressure (dizziness, lightheadedness), fast heart beat, angina
- Gallstones
- Reduction in blood platelet count (thrombocytopenia), which may result in unusual bruising or bleeding
- Increased bleeding during or after surgery
- Reduced number of red blood cells (anaemia)

There have also been rare reports of worsening of heart disease after the use of PERSANTIN. Tell your doctor as soon as possible if you experience any side effects during or after using PERSANTIN, so that these may be properly treated.

- Allergic reactions have been reported. Symptoms of an allergic reaction may include:
 - Skin rash, hives or itching
 - Swelling of the face, lips or tongue
 - Difficulty in breathing

Tell your doctor immediately if you have an allergic reaction.

You may require urgent medical attention. In addition, unexpected effects, not listed above, can occur with any medicine. You should tell your doctor or pharmacist if you notice anything unusual, during or after taking PERSANTIN.

After taking PERSANTIN

Storage

Leave all tablets in the blister pack until it is time to take a dose. The blister packaging protects the tablets. PERSANTIN 25 mg tablets should be kept in a cool, dry place where the temperature stays below 30°C. For example, do not leave your tablets in a car or store them in the bathroom. Heat and dampness will damage the tablets.

Leave all capsules in the container until it is time to take a dose. The container will protect the capsules. PERSANTIN PL 150 mg capsules should be kept in a cool, dry place where the temperature stays below 25°C. For example, do not leave your capsules in a car or store them in the bathroom. Heat and dampness will damage the capsules.

Keep PERSANTIN where children cannot reach them.

Disposal

If you have been told by your doctor that you will not be needing PERSANTIN tablets or capsules anymore, or they have passed their expiry date, the unused medicine should be returned to your pharmacist so that it can be disposed of safely.

Product Description

What the medicine look like

PERSANTIN 25 mg is the brand name of the tablets prescribed for you by your doctor. They are round, orange, shiny, biconvex sugar-coated tablets. PERSANTIN 25 mg tablets are available in packs of 84 tablets.

PERSANTIN PL 150 mg is the brand name of the capsules prescribed for you by your doctor. One half of the capsule is pink and the other half is white. PERSANTIN PL 150 mg capsules are available in packs of 60 capsules.

Ingredients

Each PERSANTIN 25 mg tablet contains 25 mg of dipyridamole. The other ingredients are lactose monohydrate, maize starch, soluble starch, silica colloidal anhydrous, magnesium stearate, sunset yellow fcf (E110), sucrose, talc, acacia, titanium dioxide (E171), macrogol 6000, beeswax and carnauba wax.

Each PERSANTIN PL 150 mg capsule contains 150 mg of dipyridamole in a sustained-release formulation. The other ingredients are tartaric acid, povidone, methacrylic acid copolymer (Eudragit S 100), talc, acacia, hypromellose, hypromellose phthalate, glycerol triacetate, dimethicone, stearic acid, gelatin, and the colouring agents titanium dioxide and iron oxide red (CI77491).

Manufacturer

PERSANTIN 25 mg tablets are made in France and PERSANTIN PL 150 mg capsules are made in Germany. They are supplied in New Zealand by:

BOEHRINGER INGELHEIM (N.Z.) LIMITED

Auckland

New Zealand

Ph 0800 802461

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