Persantin[®] Ampoules

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Persantin Ampoules?

Persantin Ampoules contain the active ingredient dipyridamole. Persantin Ampoules are used as a tool in detecting potential problems on how the heart functions in times of stress.

For more information, see Section 1. Why am I using Persantin Ampoules? in the full CMI.

2. What should I know before I use Persantin Ampoules?

Do not use if you have ever had an allergic reaction to dipyridamole or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Persantin Ampoules? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Persantin Ampoules and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Persantin Ampoules?

- Your doctor will decide what dose you will receive, based on your body weight.
- Persantin Ampoules are given as an infusion (drip) into your veins, over several minutes.

More instructions can be found in Section 4. How do I use Persantin Ampoules? in the full CMI.

5. What should I know while using Persantin Ampoules?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Persantin. Tell your doctor if you are pregnant or if you think you may be pregnant or are breast-feeding. Tell your doctor if you have or have had any of the following medical conditions: any heart condition or heart disease asthma, high or low blood pressure unexplained fainting or mini-stroke severe muscle disease (myasthenia gravis).
Things you should not do	 You should not be given this medicine in states of shock or collapse. You should not be given this medicine if you have any serious heart conditions You should not be given this medicine if you are pregnant or are breast-feeding
Looking after your medicine	 Persantin Ampoules will be stored in the pharmacy or ward below 25°C. Each ampoule can only be used once and unused contents of opened ampoules must be discarded.

For more information, see Section 5. What should I know while using Persantin Ampoules ? in the full CMI.

6. Are there any side effects?

Tell your doctor or nurse as soon as possible if you experience any side effects during or after treatment with Persantin Ampoules, so that these may be properly treated. These side effects include:

- angina
- heart attack, heart failure
- stroke or mini-stroke
- changes in heart beat (faster, slower or irregular).

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Persantin[®] Ampoules

Active ingredient: dipyridamole

Consumer Medicine Information (CMI)

This leaflet provides important information about using Persantin Ampoules. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Persantin Ampoules.

Where to find information in this leaflet:

- 1. Why am I using Persantin Ampoules?
- 2. What should I know before I use Persantin Ampoules?
- 3. What if I am taking other medicines?
- 4. How do I use Persantin Ampoules?
- 5. What should I know while using Persantin Ampoules?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Persantin Ampoules?

Persantin Ampoules contains the active ingredient dipyridamole. Persantin is a heart medicine. Persantin increases blood flow to the heart by causing the bloodsupplying arteries to widen.

Persantin Ampoules are used as a tool in detecting potential problems on how the heart functions in times of stress. It is therefore useful in predicting the likelihood of the risks of heart disease.

2. What should I know before I am given Persantin Ampoules?

Warnings

You should not be given Persantin Ampoules if:

- you are allergic to dipyridamole, or any of the ingredients listed at the end of this leaflet.
 - Always check the ingredients to make sure you can use this medicine.
- you are in states of shock or collapse.
- you have any serious heart conditions such as:
 - o heart attack or failure
 - o angina
 - abnormal changes in rhythm or rate of the heart beat (irregular, fast or slow)
 - o heart valve problems
 - o blockage of the lung artery
 - inflammation of the heart muscle (myocarditis), inner lining of the heart (endocarditis) or membrane enclosing the heart (pericarditis)
 - o tear in the wall of the aorta (major artery in the body).

Check with your doctor if you:

- have or have had any of the following medical conditions:
 any heart condition or heart disease
 - o asthma
 - o high or low blood pressure
 - o unexplained fainting or mini-stroke
 - severe muscle disease (myasthenia gravis).
 - o take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

You should not be given this medicine if you are pregnant or are breast-feeding.

It may affect your developing baby if you have it during pregnancy.

The active ingredient in Persantin passes into breast milk.

Children and adolescents

This medicine should not be given to a child.

There is limited information about the use of Persantin Ampoules in children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Persantin and affect how it works.

In particular tell your doctor if you are taking:

- aspirin
- any medicine containing dipyridamole (e.g. Persantin® SR or Asasantin® SR capsules)
- medicines used to thin your blood such as warfarin
- medicines used to treat asthma, bronchitis and emphysema such as theophylline
- medicines used to treat high blood pressure
- neostigmine, distigmine and related medicines (used, for example, in the treatment of myasthenia gravis)
- medicines used to treat rapid heart rhythm such as adenosine

You may need different amounts of your medicines, or you may need to take different medicines.

Avoid drinks such as tea, coffee and cola (which contain caffeine) for 24 hours before treatment with Persantin Ampoules.

This is because the caffeine in these drinks can decrease the effects of the medicine..

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Persantin Ampoules.

4. How am I given Persantin Ampoules?

How much is given

- Persantin Ampoules are given as an infusion (drip) into your veins, over several minutes.
- Your doctor will decide what dose you will receive, based on your body weight.

PERFUSION IMAGING:

 The recommended dose is 0.14 mg/kg/min (0.56 mg/kg total) infused over 4 minutes.

STRESS ECHO TESTING:

The recommended dose is 0.56 mg/kg over a 4 minute period, followed by 4 minutes of no dose, and if echo monitoring shows no changes, by an additional 0.28 mg/kg over 2 minutes. The cumulative dosage is 0.84 mg/kg over 10 minutes. The protocol may also be given in 6 minutes.

If you are given too much Persantin Ampoules

As Persantin Ampoules are given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Symptoms of an 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.

Tell your doctor or nurse immediately if you experience any signs of overdose, or, if you are not in hospital, go to the Emergency department at your nearest hospital.

You may need urgent medical attention.

5. What should I know while using Persantin Ampoules?

Things you must do

Tell your doctor if you are pregnant or if you think you may be pregnant or are breast-feeding

Call your doctor straight away if you:

 do not feel well while you are being given Persantin Ampoules.

Remind any doctor, dentist or pharmacist you visit that you are using Persantin Ampoules.

Looking after your medicine

 Persantin Ampoules will be stored in the pharmacy or ward below 25°C. Each ampoule can only be used once and unused contents of opened ampoules must be discarded.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Persantin must not be used after the expiry date printed on the pack or ampoule or if the packaging is torn or shows signs of tampering..

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Some of the side effects of Persantin are related to the way the medicine works on the heart and circulation. Persantin causes widening of the arteries and if these widen too much there may be a fall in blood pressure which may cause problems with the blood circulation.

Less serious side effects

Less serious side effects	What to do
 headache vomiting, nausea, diarrhoea muscle aches and pains dizziness stomach pain tingling or numbness of the hands or feet hot flushes 	Speak to your doctor or nurse if you have any of these side effects during or after treatment with Persantin Ampoules, so that these may be properly treated.

Serious side effects

Serious side effects	What to do
 angina heart attack heart failure stroke or mini-stroke changes in heart beat (faster, slower or irregular). Allergic reaction. Symptoms are rash, hives, difficulty in breathing, and swelling of the face, lips, mouth, etc fits/convulsions sudden collapse 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/</u> <u>reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available with a doctor's prescription.

What Persantin Ampoules contain

Active ingredient

Dipyridamole 10 mg

(main ingredient)	
Other ingredients	Tartaric acid
(inactive	Macrogol 600
ingredients)	Hydrochloric acid
	Water for injections
Potential allergens	-

Do not take this medicine if you are allergic to any of these ingredients.

What Persantin Ampoules looks like

Persantin Ampoules are a clear, yellow solution. It comes in a glass ampoules. (AUST R 17934).

Who distributes Persantin Ampoules

Persantin Ampoules are supplied in Australia by:

Clinect Pty Ltd

120 - 132 Atlantic Drive

Keysborough VIC 3173

Australia

Telephone: 1800 899 005

This leaflet was prepared in January 2021.