

PYTAZEN SR*

dipyridamole

150 mg sustained release tablets.

What is in this leaflet

Please read this leaflet carefully before you start taking PYTAZEN SR.

This leaflet answers some common questions about PYTAZEN SR. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PYTAZEN SR against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What PYTAZEN SR is used for

PYTAZEN SR is used for the prevention of blood clots which may occur in people with prosthetic heart valves and reduce the risk of having another stroke (blood clot in the brain) or a heart attack (blood clot in the heart).

PYTAZEN SR contains dipyridamole, which belongs to a group of medicines called anti-thrombotic agents, which are used to prevent the formation of blood clots.

Your doctor may have prescribed PYTAZEN SR for another reason.

Ask your doctor if you have any questions about why PYTAZEN SR has been prescribed for you.

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

Before you take PYTAZEN SR

When you must not take it

Do not take PYTAZEN SR if you have an allergy to:

- dipyridamole
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing
- shortness of breath
- swelling of the face, tongue, lips, or other parts of the body
- hives on the skin, rash, or itching.

Do not use PYTAZEN SR if:

- you are allergic to dipyridamole or any of the other ingredients listed at the end of this leaflet.

Do not take this medicine if you are pregnant.

if you are pregnant, think you may be pregnant or planning to have a baby, ask your doctor for advice before taking this medicine.

Do not breastfeed if you are taking this medicine.

The active ingredient in PYTAZEN SR may pass into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to children and adolescents under the age of 18 years.

Safety and effectiveness in children and adolescents younger than 18 years have not been established.

Do not take it after the expiry date (EXP) printed on the back. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking PYTAZEN SR talk to your doctor.

Before you start to use it

Tell your doctor if:

- 1. you have allergies to:**
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
- 2. you have, or have had, the following medical conditions:**
 - angina or other heart problems
 - a recent heart attack
 - heart failure
 - a bleeding disorder
 - myasthenia gravis.
 - gall stones
- 3. you are pregnant or intend to become pregnant.**

Your doctor can discuss with you the risks and benefits involved.
- 4. you are breastfeeding planning to breastfeed.**

It is not known if PYTAZEN SR passes into breastmilk. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking PYTAZEN SR.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is

prescribing a new medication for you that you are taking PYTAZEN SR.

Some medicines may interfere with PYTAZEN SR. These include:

- adenosine, for heart problems or testing
- blood thinning medicines, such as warfarin and heparin
- medicines used to treat high or low blood pressure
- medicines for muscle weakness, e.g. cholinesterase inhibitor
- aspirin
- cefamandole, cefoperazone, moxalactam – medicines used to treat bacterial infections
- sodium valproate – a medicine used to treat epilepsy
- pentoxifylline – a medicine used to improve blood flow in peripheral blood vessels
- plasminogen activators such as streptokinase and urokinase
- cytotoxic agents.

These medicines may be affected by PYTAZEN SR or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking PYTAZEN SR.

How to take PYTAZEN SR

How much to take

Carefully follow all directions given to you by your doctor. Their directions may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Follow all directions given to you by your doctor or pharmacist carefully. Your doctor may have prescribed a different dose.

The standard dose for this medicine is ONE tablet TWO times daily with water.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

If you take the wrong dose, PYTAZEN SR may not work as well.

How to take it

PYTAZEN SR tablets should be taken whole with some water, independently of meals or as directed by your doctor or pharmacist. The tablets must not be chewed, crushed, halved or broken up.

Do not take PYTAZEN SR tablets with alcohol.

When to take it

Take PYTAZEN SR once in the morning, and once in the evening at the same time each day.

Take PYTAZEN SR at about the same time each day.

Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps you control your condition but does not cure it. Therefore, you must take it every day.

If you forget to take it

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

If you are not sure what to do, ask your doctor or pharmacist.

While you are taking PYTAZEN SR

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking PYTAZEN SR.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Things you must not do

Do not give PYTAZEN SR tablets to anyone else, even if they have the same condition as you.

Do not take PYTAZEN SR at the same time as an alcoholic drink.

Do not stop taking PYTAZEN SR, or lower the dosage, without checking with your doctor. Your doctor may want you to gradually reduce the amount you are taking before stopping completely.

Things to be careful of

Be careful driving or operating machinery until you know how PYTAZEN SR affects you. It may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

Be careful if you are over 65 and unwell or taking other medicines. Some people may experience side effects such as dizziness and unsteadiness, which may increase the risk of a fall.

Be careful when drinking alcohol while you are taking this medicine.

Taking alcohol at the same time, or just before or soon afterwards may affect how PYTAZEN SR is released from the tablet.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much PYTAZEN SR.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Signs of an overdose include feeling warm, flushes, sweating, restlessness, feelings of weakness and dizziness, chest pain, drop in blood pressure and fast heartbeat.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PYTAZEN SR.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

The list below includes the more common side effects of your medicine:

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

- bleeding after an operation
- muscle pain
- rash
- stomach pain
- being sick (vomiting).

Tell your doctor as soon as possible if you notice any of the following symptoms:

- worsening of symptoms of heart disease such as chest pain, increased heartrate, fatigue, and breathlessness
- thrombocytopenia which can cause bruising and prolonged bleeding.

If any of the following happen, stop taking PYTAZEN SR and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- hives
- fainting.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to PYTAZEN SR. You may need urgent medical attention or hospitalisation. These side effects are very rare.

These may be serious side effects of PYTAZEN SR. You may need urgent medical attention. Serious side effects are uncommon.

Tell your doctor if you notice any other effects. Other adverse effects not listed above may also occur in some patients.

After taking PYTAZEN SR

Storage

Keep your tablets in the bottle until it is time to take them. If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays at or below 25°C.

Do not store PYTAZEN SR in the bathroom or near a sink. Do not leave it in the car or on a windowsill. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

Product description

What it looks like

PYTAZEN SR 150 mg modified release tablet: yellow capsule shaped tablet of 14 mm length and 6 mm in width with a score on one side and comes in bottles of 60 tablets.

Ingredients

Active ingredient(s):

- dipyridamole 150 mg

Inactive ingredients:

- acetone
- calcium phosphate (monobasic)
- ethanol
- hypromellose
- isopropyl alcohol
- macrogol 4000
- magnesium stearate
- methacrylic acid copolymer
- purified talc
- quinolone yellow
- titanium dioxide.

Sponsor details

PYTAZEN SR is supplied in New Zealand by:
Douglas Pharmaceuticals Ltd

P O Box 45 027
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New Zealand
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Date of preparation

This leaflet was prepared on 10 July 2024
(based on data sheet dated 10 July 2024)