

PATIENT INFORMATION LEAFLET

DIPYRIDAMOLE 50 mg/5 ml ORAL SUSPENSION Dipyridamole

Read all of this leaflet carefully before you start taking this medicine - Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

What is in this leaflet:

- What Dipyridamole is and what it is used for
- What you need to know before you take Dipridamole
- How to take Dipyridamole Possible side effects

- How to store Dipyridamole Contents of the pack and other information

WHAT DIPYRIDAMOLE IS AND WHAT IT IS USED FOR

Dipyridamole belongs to a group of medicines called anti-platelet agents. Dipyridamole 50 mg/5 ml Oral Suspension ("Dipyridamole") helps to prevent the formation of blood clots which sometimes occur if you have artificial heart valves.

WHAT YOU NEED TO KNOW BEFORE YOU TAKE DIPYRIDAMOLE

DO NOT take Dipyridamole

if you are allergic (hypersensitive) to dipyridamole or any of the other ingredients in the product (see Section 6 and end of Section 2).

Warnings and precautions

Talk to your doctor if you have

- narrowed or blocked arteries, angina, heart valve, circulation or other heart problems, or if you have had a recent heart attack myasthenia gravis (a nerve disease which causes muscle weakness) as your medicines may need to be adjusted
- any blood clotting disorders
- a hereditary intolerance to fructose
- planned to become pregnant, are pregnant or breast-feeding.

Dipyridamole is sometimes given as an injection during some tests on your heart (e.g. myocardial imaging). If this applies to you, tell your doctor that you are already taking Dipyridamole. You may be advised to stop taking your usual medicine 24 hours before your test.

Other medicines and Dipyridamole
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, but

- particularly if you are taking:

 adenosine (e.g. for heart problems)
 - medicines for high blood pressure
 - aspirin, because the effects on blood platelets may be increased
- any drug for myasthenia gravis (a nerve disease that causes muscle weakness) because your medicines may need to be adjusted any other medicines to prevent blood clots forming (e.g. warfarin). Tell the anticoagulant clinic at your next visit that you are now
- taking Dipyridamole
- medicine to reduce stomach acid (e.g. antacids for indigestion).

Dipyridamole with food and drink

It is best to take this medicine before meals

Pregnancy and breast-feeding

Tell your doctor if you are pregnant or planning to become pregnant. Tell your doctor if you are breast-feeding as Dipyridamole should only be used during breast-feeding if your doctor considers it essential.

- Important information about some of the ingredients of this medicine
 Dipyridamole 50 mg/5 ml Oral Suspension contains:

 Liquid Maltitol (E965): If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This product contains 2.8 g maltitol per 5 ml of suspension and may have a mild laxative effect. Maltitol has a calorific value of 2.3 kcal/o
- Methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and ethyl parahydroxybenzoate (E214): may cause allergic reactions (possibly delayed).

HOW TO TAKE DIPYRIDAMOLE

Always take Dipyridamole exactly as your doctor has told you. You should check with your doctor if you are not sure about the dose you

This medicine should only be taken by mouth and just before meals. Shake the bottle thoroughly before use, as the contents may settle.

Usual doses are

Adults:	Between
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- Two (5 ml) spoonfuls 3 times a day and

 Three (5 ml) spoonfuls 4 times a day.
 Your doctor will advise on the best dose for you. (The maximum recommended daily dose is 600 mg or 12 spoonfuls).

Children: Not recommended for use

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DUMMY

VENDOR CODE TO BE PRINTED AT THE BOTTOM RIGHT HAND CORNER OF FRONT AND BACK PAGE

PRINT FREE AREA

BLEED AREA

INSERT PIPS FRONT AND BACK FOR BLANK SHEET DETECTION AT PRINT



If you take more Dipyridamole than you should
If you have taken more Dipyridamole than you should, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet and/or the bottle with you.

If you forget to take Dipyridamole
If you miss a dose, take it as soon as you remember and then take any remaining doses that day at evenly spaced intervals. Do not take a double dose to make up for the forgotten dose.

POSSIBLE SIDE EFFECTS

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

You should STOP using Dipyridamole and contact your doctor immediately if you experience a rare allergic reaction, including swelling of the face and neck or skin rashes, difficulty breathing, loss of consciousness, and fever or shock.

The following side effects usually only occur early in your treatment:

- being, or feeling sick diarrhoea
- dizziness
- feeling faint
- indigestion headache
- myalgia (muscular pain).

Dipyridamole may act to widen your blood vessels which can cause:

- hot flushes
- lowering of blood pressure (hypotension). You may feel light-headed or faint.
- increased heart rate
- worsening of the symptoms of heart disease (e.g. chest pain and irregular heart rhythm).

If you have gallstones, dipyridamole has been found in them

Very rarely, the following symptoms have been reported

- increased bleeding during or after surgery a blood disorder causing bruising and extending your blood clotting time (thrombocytopenia).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can aslo report side effects directly via the national reporting systems listed below:

United Kingdom Yellow Card Scheme

Website: http://www.mhra.gov.uk/yellowcard

IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie

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

HOW TO STORE DIPYRIDAMOLE

Keep out of the reach and sight of children. Store in the original packaging. Do not store above 25°C. Do not use Dipyridamole after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month. Use within 30 days of first opening.

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 protect the environment.

CONTENTS OF THE PACK AND OTHER INFORMATION

This product contains:

the active ingredient: dipyridamole (50 mg in 5 ml of the suspension).

other ingredients: magnesium aluminium silicate, xanthan gum, glycerol (E422), liquid maltitol (E965), disodium phosphate dodecahydrate, saccharin sodium, banana flavour, polysorbate 80, simeticone, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), ethyl parahydroxybenzoate (E214), propylene glycol, citric acid monohydrate, purified water. (See end of Section 2 for further information).

What Dipyridamole looks like and contents of the pack
Dipyridamole 50 mg/5 ml Oral Suspension is a yellow sugar free suspension with a banana flavour and odour, and is available in amber glass bottles of 150 ml.

Marketing Authorisation Holder and Manufacturer Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

This medicinal product is authorised in the Member States of the EEA under the following names:

Dipyridamole 50 mg/5 ml Oral Suspension Dipyridamole 50 mg/5 ml Oral Suspension

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