

## **Package leaflet: Information for the user Dipyridamole 200mg/5ml Oral Suspension**

**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. See section 4.

The name of your medicine is Dipyridamole 200mg/5ml Oral Suspension but it will be referred as Dipyridamole throughout this leaflet.

### **What is in this leaflet**

- 1. What Dipyridamole is and what it is used for**
- 2. What you need to know before you take Dipyridamole**
- 3. How to take Dipyridamole**
- 4. Possible side effects**
- 5. How to store Dipyridamole**
- 6. Contents of the pack and other information**

#### **1. What Dipyridamole is and what it is used for**

Dipyridamole belongs to a group of medicines called ‘anti-thrombotic agents’, which are used to help stop blood clots forming.

Dipyridamole helps stop blood clots which may occur if you have had your heart valves replaced.

You must talk to a doctor if you do not feel better or if you feel worse.

#### **2. What you need to know before you take Dipyridamole**

##### **Do not take Dipyridamole if:**

- ▶ You are allergic to dipyridamole or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Dipyridamole if:

- ▶ you have angina or other heart problems (including heart valve or circulation problems) or have had a recent heart attack
- ▶ you have myasthenia gravis (a rare muscle problem)
- ▶ you have any bleeding problems
- ▶ you are pregnant or planning to become pregnant or are breast feeding
- ▶ you have been told by your doctor that you have an intolerance to some sugars.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Dipyridamole.

### **Other medicines and Dipyridamole**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine. This includes medicines obtained without a prescription and herbal medicines. Dipyridamole may affect or be affected by other medicines.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- ▶ Medicines for high blood pressure
- ▶ Medicines for muscle weakness such as something called a ‘cholinesterase inhibitor’
- ▶ Antacids - for indigestion
- ▶ Aspirin (or planning to take aspirin for any condition) or other anti-platelet agents which are used to prevent blood clot formation
- ▶ Adenosine injection - used for heart problems or tests on the heart
- ▶ Warfarin or other medicines to stop blood clots forming. If so, tell them at your next visit to the anticoagulant clinic that you are now taking Dipyridamole.

### **If you are having heart tests**

Dipyridamole is also sometimes given as an injection during tests to see if the heart is working properly (also called ‘myocardial imaging’). This means that the test and your medicine may contain the same substance. If you are going to have an injection of dipyridamole, tell the doctor that you are taking Dipyridamole.

### **Pregnancy and Breast-feeding**

- ▶ If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
- ▶ Tell your doctor if you are breast-feeding or about to start breast-feeding as Dipyridamole should only be used during breast-feeding if your doctor considers it essential.

### **Driving and using machines**

You may feel dizzy while taking Dipyridamole. If this happens do not drive or use any tools or machines.

### **Dipyridamole contains:**

**Maltitol liquid (E965):** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**Methyl (E218) and propyl parahydroxybenzoates (E216):** May cause allergic reactions (possibly delayed).

**Propylene glycol (E1520):** This medicine contains 545.20mg propylene glycol in each 5ml which is equivalent to 109.04mg/ml.

**Sodium:** This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'.

**Benzoic acid (E210):** This medicine contains 0.05mg benzoic acid in each 5ml which is equivalent to 0.01mg/ml.

## **3. How to take Dipyridamole**

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

### **The usual dose is:**

- ▶ The usual dose is 300-600mg each day.
- ▶ This is taken in three or four separate doses.

- ▶ The most you can take in a day is 600mg (which is a total of 15mls per day).
- ▶ It is best to take the Dipyridamole before meals.

Do not give to children.

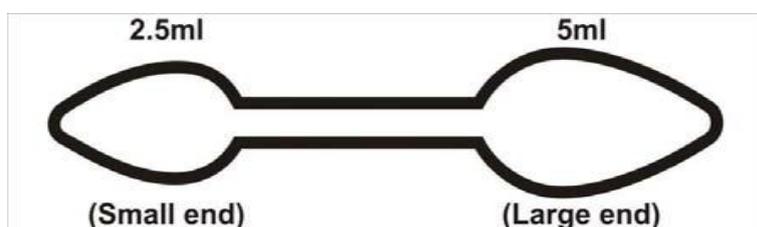
### **Route and Method of administration**

This medicinal product must be taken orally.

This product may settle during storage. Shake well before use.

- ▶ Use only the dosing spoon supplied with the pack (see figure below).
- ▶ Measure the exact quantity of dipyridamole using the dosing spoon, 2.5ml (small end) contains 100mg of dipyridamole, and 5ml (large end) contains 200mg of dipyridamole.
- ▶ Swallow the suspension.
- ▶ Wash the spoon with clean water after taking every dose.

### **2.5-5ml double-ended spoon**



### **If you take more Dipyridamole than you should**

Call your doctor or go to your nearest hospital casualty department straight away. Take the medicine pack with you, even if there is no Dipyridamole left.

### **If you forget to take Dipyridamole**

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

### **If you stop taking Dipyridamole**

Do not stop taking Dipyridamole unless your doctor tells you to.

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

## **4. Possible side effects**

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

### **Allergic reactions:**

If you have an allergic reaction, stop taking your medicine and see a doctor straight away. The signs may include feeling breathless, runny nose, severe rash with itching, swelling and swelling around the eyes.

Other side effects that have been reported for Dipyridamole are:

### **Very common (may affect more than 1 in 10 people)**

- ▶ Headache
- ▶ Feeling dizzy
- ▶ Feeling sick (nausea)

- ▶ Diarrhoea

### **Common (may affect up to 1 in 10 people)**

- ▶ Muscle pain
- ▶ Being sick (vomiting)
- ▶ Worsening of the symptoms of heart disease such as chest pain and shortness of breath

### **Not known (frequency cannot be estimated from the available data)**

- ▶ Hot flushes
- ▶ Lowering of blood pressure
- ▶ A blood problem called ‘thrombocytopenia’ which can cause bruising and prolonged bleeding from wounds, including during or after surgery

In people who have gallstones, the dipyridamole in this medicine can be absorbed into the gallstones.

If any of the side effects gets troublesome or serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Dipyridamole**

- ▶ Keep this medicine out of the sight and reach of children.
- ▶ Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.
- ▶ Do not store above 25°C.
- ▶ Discard 60 days after first opening.
- ▶ Do not use this medicine if you notice that the suspension becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- ▶ Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Dipyridamole contains**

The active substance is dipyridamole.

Each 5ml of oral suspension contains 200mg dipyridamole.

The other ingredients are methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), polysorbate 80 (E433), simeticone emulsion 30% (containing polydimethylsiloxane, sorbitan monostearate, polyoxyethylene 20 sorbitan, silicon dioxide, xanthan gum, benzoic acid, sorbic acid, potassium hydroxide, hydrogen chloride and deionised water), liquid maltitol (E965), xanthan gum (E415), aluminium magnesium silicate (E553a), citric acid monohydrate (E330), disodium phosphate anhydrous (E339), ammonium glycyrrhizinate,

propylene glycol (E1520), orange flavour [containing propylene glycol (E1520)] and purified water.

**What Dipyridamole looks like and contents of the pack**

Dipyridamole is a uniform yellow coloured suspension with orange flavour supplied in an amber glass bottle with a tamper evident child resistant plastic cap and a 2.5ml-5ml double-ended plastic spoon for measuring and administering the dose.

Dipyridamole is supplied in bottles containing 150ml and 300ml of oral suspension. Not all pack sizes may be marketed.

**POM**

**Marketing Authorisation Holder:**

Syri Pharma Limited t/a Thame Laboratories  
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1 Windmill Lane,  
Dublin 2, D02 F206, Ireland.

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**OR**

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Paola PLA3000, Malta.

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