SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

PYRIDANTIN / Dipyridamole BP 25 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dipyridamole BP 25 mg

3 PHARMACEUTICAL FORM

Sugar-coated tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

1. As an adjunct to oral anti-coagulation for prophylaxis of thromboembolism associated with prosthetic heart valves.

2. In combination with aspirin for:

a. Prophylaxis of deep venous thrombosis as an alternative to subcutaneous heparin, other than in hip surgery.

b. Prophylaxis of recurrent venous thrombosis resistant to oral anti-coagulation.

c. Prophylaxis of occlusion following prosthetic arterial grafts and coronary artery bypass grafts.

4.2 Posology and method of administration

Adults:	300-600 mg daily in three or four doses.
Children:	The normal total oral daily dose is 5 mg/kg bodyweight in divided doses.
Elderly:	As for adults.

PYRIDANTIN is taken by mouth, and should usually be taken before meals.

4.3 Contraindications

Patients with a known hypersensitivity to Dipyridamole. Patients with known cardiac conduction difficulties or dysrhythmias.

4.4 Special warnings and precautions for use

PYRIDANTIN should be used with caution in patients with coagulation disorders. PYRIDANTIN is a potent vasodilator and should be used with caution in patients with rapidly worsening angina, sub-valvular aortic stenosis or haemodynamic instability associated with a recently sustained myocardial infarction.

4.5 Interaction with other medicinal products and other forms of interaction

The effect of adenosine is enhanced and extended by dipyridamole. The concurrent use of antacids may reduce the efficacy of PYRIDANTIN. PYRIDANTIN may enhance the effects of oral anticoagulants.

4.6 Pregnancy and lactation

PYRIDANTIN should not be used in pregnancy, especially for the first trimester, unless the expected benefit is thought to outweigh any possible risk to the foetus.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

If these occur it is usually during the early part of treatment and they are often dose-related. The vasodilating properties of PYRIDANTIN may occasionally produce a vascular headache which normally disappears with dosage reduction. Dizziness, faintness, dyspepsia, mild diarrhoea, myalgia, hypotension, hot flushes and tachycardia have also been reported occasionally.

In rare cases worsening symptoms of coronary heart disease; hypersensitivity reactions such as rash, urticaria, severe bronchospasm and angioedema; increased bleeding during or after surgery and thrombocytopenia have been reported.

4.9 Overdose

Overdosage may lead to headache, gastro-intestinal symptoms and hypotension. Coronary vasodilation may cause chest pain in patients with ischaemic heart disease. General supportive measures should be employed. Coronary vasodilation may be reversed by administering aminophylline by slow IV injection.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The antithrombotic activity of phosphodiesterase inhibitors, such as Dipyridamole, depend upon the activation of platelet adenylcyclase by potentiation of endogenous prostacyclin. Dipyridamole inhibits platelet function through its effect on prostacyclin metabolism in platelets.

5.2 Pharmacokinetic properties

Dipyridamole is readily absorbed from the gastro-intestinal tract. It is concentrated in the liver and is mainly excreted in the faeces. Excretion may be delayed by reabsorption. A small amount is excreted in the urine as glucuronide.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

lactose
maize starch
povidone
pregelatinised starch
magnesium stearate
bleached shellac
sucrose
talc
titanium dioxide
beeswax
carnauba wax
orange colour

6.2 Incompatibilities

Sensitivity to Dipyridamole or any of the other ingredients of PYRIDANTIN. The concurrent use of antacids may reduce the efficacy of PYRIDANTIN.

6.3 Shelf life

36 Months (all pack sizes).

6.4 Special precautions for storage

Store below 25°C in well closed containers. Protect from light.

6.5 Nature and contents of container

Polypropylene or high density polystyrene with polythene closure and polyurethane wads or polythene inserts.

Packs of 28, 30, 50, 56, 60, 84, 100, 250, 500 & 1000 tablets.

PVC/Aluminium foil blister packs 250 micron PVC glass-clear bluish rigid PVC (Pharmaceutical grade). 20 micron hard-tempered aluminium foil coated on the dull side with 6-7 gsm heat-seal lacquer and printed on the bright side.

Packs of 28, 30, 50, 56, 60, 84, 100, 250, 500 & 1000 tablets.

6.6 Special precautions for disposal

No special instructions.

7 MARKETING AUTHORISATION HOLDER

Chelonia Healthcare Limited
11 Boumpoulinas Street,
3rd floor, 1060 Nicosia
Cyprus

8 MARKETING AUTHORISATION NUMBER(S)

PL 33414/0041

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/12/2004

10 DATE OF REVISION OF THE TEXT

17/02/2009