Product Summary

1. **NAME OF THE MEDICINAL PRODUCT**
   
   Dipyridamole 25mg Tablets

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**
   
   Dipyridamole 25 mg per tablet
   See 6.1 for excipients

3. **PHARMACEUTICAL FORM**
   
   Coated tablet

4. **CLINICAL PARTICULARS**

   4.1. **Therapeutic indications**
   
   As an adjunct to oral anti-coagulation for prophylaxis of thromboembolism associated with prosthetic heart valves.

   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 and the elderly: 300-600 mg daily in three or four doses.
   Children: The normal total oral daily dose is 5mg/kg bodyweight in three to four equal doses.
   Route of administration: Oral use (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

Dipyridamole is a potent vasodilator. It should be used with caution in patients with hypotension, severe coronary artery disease including unstable angina or recent myocardial infarction, left ventricular outflow obstruction such as aortic stenosis, and in patients with decompensated heart failure.

Dipyridamole should be used with caution in patients with coagulation disorders.

Oral dipyridamole should be stopped 24 hours before intravenous use for stress testing.

In patients with myasthenia gravis readjustment of therapy may be necessary after changes in dipyridamole dosage (see Section 4.5).

The tablets contain sunset yellow, E110 which can cause allergic-type reactions including asthma. Allergy is more common in those people who are allergic to aspirin.

This product contains lactose and sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

4.5 Interactions with other medicinal products and other forms of interaction

The concurrent use of antacids may reduce the efficacy of Dipyridamole Tablets. Dipyridamole Tablets may enhance the effects of oral anticoagulants.

4.6 Pregnancy and lactation

Dipyridamole Tablets 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

Adverse reactions at therapeutic doses are usually mild. If these occur it is usually in the beginning of treatment and they are often dose-related.

Hypersensitivity reactions such as rash, urticaria, severe bronchospasm and angioedema have been reported.
The vasodilating properties of Dipyridamole Tablets may occasionally produce a throbbing headache which normally disappears with dosage reduction.

**ADVERSE REACTIONS REPORTED IN PATIENTS TAKING DIPYRIDAMOLE**

The following adverse reactions have been reported in patients taking dipyridamole. The adverse reactions are classified according to frequencies determined from postmarketing experience and reference literature.

Very common \( \geq 1/10 \) (\( \geq 10\% \))
Common \( \geq 1/100 \) and \(<1/10 \) (\( \geq 1\% \) and \(<10\% \))
Uncommon \( \geq 1/1000 \) and \(<1/100 \) (\( \geq 0.1\% \) and \(<1\% \))
Rare \( \geq 1/10,000 \) and \(<1/1000 \) (\( \geq 0.01\% \) and \(0.1\% \))
Very rare \(< 1/10,000 \) (\( <0.1\% \))

**Immune System Disorders**
Uncommon: Hypersensitivity reaction

**Nervous System Disorders**
Common: Headache, dizziness
Uncommon: Fainting

**Cardiac Disorders**
Uncommon: Angina pectoris aggravated, cardiac arrhythmia

**Vascular Disorders**
Common: Hypotension, facial flushing

**Gastrointestinal Disorders**
Common: Nausea, diarrhoea
Uncommon: Vomiting

**Skin and Subcutaneous Tissue Disorders**
Uncommon: rash

**General Disorders and Administration Site Conditions**
Uncommon: Chest pain

In very rare cases, increased bleeding during or after surgery has been observed. Isolated cases of thrombocytopenia have been reported in conjunction with treatment with dipyridamole.

**4.9 Overdose**

Due to the low number of observations, experience with dipyridamole overdose is limited.

Symptoms such as a warm feeling, flushes, sweating, restlessness, feeling of weakness, dizziness, hypotension and angina complaints can be expected. 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 of xanthine derivatives (e.g. aminophylline).
Due to its wide distribution to tissues and its predominantly hepatic elimination, dipyridamole is not likely to be accessible to enhanced removal procedures.

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

No additional data relevance to prescriber

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

<table>
<thead>
<tr>
<th>Core:</th>
<th>Coating:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose</td>
<td>Bleached shellac</td>
</tr>
<tr>
<td>Maize starch</td>
<td>Sucrose</td>
</tr>
<tr>
<td>Povidone</td>
<td>Talc</td>
</tr>
<tr>
<td>Pregelatinised starch</td>
<td>Titanium dioxide E171</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Beeswax</td>
</tr>
<tr>
<td></td>
<td>Carnauba Wax</td>
</tr>
<tr>
<td></td>
<td>Sunset yellow E110</td>
</tr>
</tbody>
</table>

6.2. Incompatibilities

Sensitivity to Dipyridamole or any of the other ingredients of Dipyridamole Tablets. The concurrent use of antacids may reduce the efficacy of Dipyridamole Tablets. Dipyridamole Tablets may enhance the effects of oral anticoagulants.
6.3. **Shelf life**

3 Years (all pack sizes)

6.4. **Special precautions for storage**

Do not store above 25°C. Keep container tightly closed (for containers). Store in the original package (for blisters).

6.5. **Nature and contents of container**

Cylindrical polypropylene containers with polythene lids and polyurethane or polythene inserts or PVC/Aluminium foil blister packs.
Pack sizes: 28, 30, 50, 56, 60, 84, 100, 250, 500 & 1000 tablets.

6.6. **Instruction for use and handling (and disposal)**

No special instructions.

No Data Held

**Administrative Data**

7. **MARKETING AUTHORISATION HOLDER**

Dr. Reddy’s Laboratories (UK) Ltd
6 Riverview Road
Beverley
East Yorkshire
HU 17 0LD
United Kingdom

8. **MARKETING AUTHORISATION NUMBER**

PL 08553/0079

9. **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

10/12/2003
DATE OF REVISION OF THE TEXT

27/10/2010