

# Material Safety data sheet

## DIPYRIDAMOLE TABLETS, USP

Strength: 25 /50 / 75 mg.

Pack Size: Bottle of 100/500/1000 Tablets  
Blister of 100 Tablets

Revision No.: 00

### EMERGENCY OVERVIEW

DIPYRIDAMOLE TABLETS, USP contain Dipyridamole and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

## Section 1. Identification of the substance

### Identification of the product

Product name:	Dipyridamole Tablets USP
Formula:	C <sub>24</sub> H <sub>40</sub> N <sub>8</sub> O <sub>4</sub>
Chemical Name:	2,2',2'',2'''-[(4,8-Dipiperidinopyrimido[5,4-d]pyrimidine-2,6-diyl)dinitrilo]-tetraethanol.
Therapeutic Category	Platelet inhibitor

### Manufacturer / supplier identification

Company:	Cadila Healthcare Ltd. Ahmedabad, India
Contact for information:	Tel.: +91 79 6868100 Fax: +91 79 3750319
Emergency telephone No.	Tel.: +91 79 6868100

## Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
<b>Principle Component :</b>		
Dipyridamole	Not Found	58-32-2
<b>Inactive Ingredients :</b>		
Corn starch,	Not Found	9005-25-8
Hypromellose,	Not Found	9004-65-3
Iron oxide yellow,	Not Found	51274-00-1
Lactose monohydrate,	Not Found	63-42-3
Magnesium stearate,	Not Found	557-04-0
Polyethylene glycol,	Not Found	25322-68-3
Povidone	Not Found	9003-39-8
Titanium dioxide.	Not Found	13463-67-7

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### Section 3. Health Hazards Information

Dose and Administration	The recommended dose is 75 to 100 mg four times daily as an adjunct to the usual warfarin therapy.
Adverse Effects	Adverse reactions at therapeutic doses are usually minimal and transient. On long-term use of dipyridamole tablets initial side effects usually disappear. The Dizziness, Abdominal distress, Headache and Rash were reported in two heart valve replacement trials comparing dipyridamole tablets and warfarin therapy to either warfarin alone or warfarin and placebo. Other reactions from uncontrolled studies include diarrhea, vomiting, flushing and pruritus.
Over Dose Effect	In case of real or suspected overdose, seek medical attention or contact a Poison Control Center immediately. Careful medical management is essential. Based upon the known hemodynamic effects of dipyridamole, symptoms such as warm feeling, flushes, sweating, restlessness, feeling of weakness and dizziness may occur. A drop in blood pressure and tachycardia might also be observed.
Medical Conditions	<p><b>Coronary Artery Disease:</b> Dipyridamole has a vasodilatory effect and should be used with caution in patients with severe coronary artery disease. Chest pain may be aggravated in patients with underlying coronary artery disease who are receiving dipyridamole.</p> <p><b>Hepatic Insufficiency:</b> Elevations of hepatic enzymes and hepatic failure have been reported in association with dipyridamole administration.</p> <p><b>Hypotension:</b> Dipyridamole should be used with caution in patients with hypotension since it can produce peripheral vasodilation.</p> <p><b>Laboratory Tests:</b> Dipyridamole has been associated with elevated hepatic enzymes.</p>
Contraindications	Hypersensitivity to dipyridamole and any of the other components.
Pregnancy Comments	<p><b>Teratogenic Effects :</b> :Reproduction studies have been performed in mice, rabbits and rats at oral dipyridamole doses of up to 125 mg/kg, 40 mg/kg and 1000 mg/kg, respectively (about 1<sub>1/2</sub>, 2 and 25 times the maximum recommended daily human oral dose, respectively, on a mg/m<sup>2</sup> basis) and have revealed no evidence of harm to the fetus due to dipyridamole.</p> <p><b>Nursing Mothers:</b> As dipyridamole is excreted in human milk, caution should be exercised when dipyridamole tablets are administered to a nursing woman.</p>
Pregnancy Category	<b>B</b>

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### Section 4. First aid measures

General	Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention
Overdose Treatment	Symptomatic treatment is recommended, possibly including a vasopressor drug. Gastric lavage should be considered. Administration of xanthine derivatives (e.g., aminophylline) may reverse the hemodynamic effects of dipyridamole overdose. Since dipyridamole is highly protein bound, dialysis is not likely to be of benefit.

### Section 5. Fire – fighting measures

<b>Flash point</b>	Not Found	<b>Upper Flammable Limit:</b>	Not Found
<b>Auto-Ignition Temperature:</b>	Not Found	<b>Lower Flammable Limit:</b>	Not Found
<b>Extinguishing Media</b>	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	<b>Fire and Explosion Hazard</b>	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity.
<b>Fire Fighting Procedure</b>	As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.		

### Section 6. Storage / Spill / Disposal Measures

Storage	Store at 20°-25°C (68°-77°F) Dispense in a tight, light-resistant container.
Spill Response	Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.
Disposal	Dispose the waste in accordance with all applicable Federal, State and local laws.

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### Section 7. Exposure controls and personal protection

Respiratory Protection	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.
Skin Protection	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
Eye protection	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.

### Section 8. Physical and chemical properties

<b>Appearance</b>	Dipyridamole Tablets USP, 25 mg are light yellow, round, biconvex, film-coated tablets debossed with 'ZE 43' on one side and plain on the other side .  Dipyridamole Tablets USP, 50 mg are light yellow, round, biconvex, beveled-edge, film-coated tablets debossed with 'ZE 49' on one side and plain on the other side .  Dipyridamole Tablets USP, 75 mg are light yellow, round, biconvex, beveled-edge, film-coated tablets debossed with 'ZE 50' on one side and plain on the other side.		
<b>Solubility in water</b>	No Data Available	<b>Odour</b>	Odourless
<b>Boiling point</b>	No Data Available	<b>Melting Point</b>	No Data Available
<b>Evaporation rate</b>	No Data Available	<b>Vapour density</b>	No Data Available
<b>Reactivity in water</b>	No Data Available	<b>Evaporation rate</b>	No Data Available
<b>Percentage Volatile by volume</b>	No Data Available	<b>Specific gravity</b>	No Data Available
<b>Vapour pressure</b>	No Data Available		
<b>Other information</b>	Not Applicable		

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### Section 9. Physical Hazards

<b>Condition to avoid</b>	Avoid exposure to extreme heat, light and moisture.	<b>Stable</b>	Stable under normal ambient and anticipated storage and handling conditions.
<b>Decomposition Products</b>	No Data Available	<b>Hazardous Reaction</b>	No data available.
<b>Incompatibilities</b>	No data available.		

### Section 10. Toxicological information

General	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Target organ	Eye contact, Skin contact and inhalation is not great risk as this product is tablet.
other	Carcinogenesis, Mutagenesis, Impairment of Fertility: In studies in which dipyridamole was administered in the feed to mice (up to 111 weeks in males and females) and rats (up to 128 weeks in males and up to 142 weeks in females), there was no evidence of drug-related carcinogenesis. The highest dose administered in these studies (75 mg/kg/day) was, on a mg/m <sup>2</sup> basis, about equivalent to the maximum recommended daily human oral dose (MRHD) in mice and about twice the MRHD in rats. Mutagenicity tests of dipyridamole with bacterial and mammalian cell systems were negative. There was no evidence of impaired fertility when dipyridamole was administered to male and female rats at oral doses up to 500 mg/kg/day (about 12 times the MRHD on a mg/m <sup>2</sup> basis).

### Section 11. Ecological information

No data available on Ecotoxicity

### Section 12. Other information

None

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Supersedes edition of: New Edition

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.