

**DIPYRIDAMOLE- dipyridamole tablet, film coated**  
**Cadila Healthcare Limited**

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**Dipyridamole Tablets, USP**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 65841-662-01 in bottle of 100 tablets

Dipyridamole Tablets USP, 25 mg

R<sub>x</sub> only

100 tablets

ZYDUS



NDC 65841-663-01 in bottle of 100 tablets

Dipyridamole Tablets USP, 50 mg

R<sub>x</sub> only

100 tablets

ZYDUS

NDC 65841-664-01 in bottle of 100 tablets

Dipyridamole Tablets USP, 75 mg

R<sub>x</sub> only

100 tablets

ZYDUS

## DIPYRIDAMOLE

dipyridamole tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-662
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPYRIDAMOLE (UNII: 64ALC7F90C) (DIPYRIDAMOLE - UNII:64ALC7F90C)	DIPYRIDAMOLE	25 mg

## Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	

## Product Characteristics

Color	YELLOW (LIGHT YELLOW)	Score	no score
Shape	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	ZE;43
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-662-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2008	
2	NDC:65841-662-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2008	
3	NDC:65841-662-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2008	
4	NDC:65841-662-77	10 in 1 CARTON	05/22/2008	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040874	05/22/2008	

## DIPYRIDAMOLE

dipyridamole tablet, film coated

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-663
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPYRIDAMOLE (UNII: 64ALC7F90C) (DIPYRIDAMOLE - UNII:64ALC7F90C)	DIPYRIDAMOLE	50 mg

## Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	

## Product Characteristics

Color	YELLOW (LIGHT YELLOW)	Score	no score
Shape	ROUND (ROUND)	Size	7mm
Flavor		Imprint Code	ZE;49
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-663-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2008	
2	NDC:65841-663-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2008	
3	NDC:65841-663-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2008	
4	NDC:65841-663-77	10 in 1 CARTON	05/22/2008	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040874	05/22/2008	

## DIPYRIDAMOLE

dipyridamole tablet, film coated

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-664
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPYRIDAMOLE (UNII: 64ALC7F90C) (DIPYRIDAMOLE - UNII:64ALC7F90C)	DIPYRIDAMOLE	75 mg

## Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	

## Product Characteristics

Color	YELLOW (LIGHT YELLOW)	Score	no score
Shape	ROUND (ROUND)	Size	8mm
Flavor		Imprint Code	ZE;50
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-664-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2008	
2	NDC:65841-664-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2008	
3	NDC:65841-664-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2008	
4	NDC:65841-664-77	10 in 1 CARTON	05/22/2008	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040874	05/22/2008	

**Labeler** - Cadila Healthcare Limited (918596198)

**Registrant** - Cadila Healthcare Limited (918596198)

## Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(65841-662, 65841-663, 65841-664) , MANUFACTURE(65841-662, 65841-663, 65841-664)

## Establishment

Name	Address	ID/FEI	Business Operations
CADILA HEALTHCARE LIMITED		677605858	ANALYSIS(65841-662, 65841-663, 65841-664) , MANUFACTURE(65841-662, 65841-663, 65841-664)

