

RISPERIDONE - risperidone tablet, orally disintegrating
Zydus Lifesciences Limited

RISPERIDONE ORALLY DISINTEGRATING TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-640-06 in bottle of 30 tablets

Risperidone Orally Disintegrating Tablets, 0.5 mg

Rx only

30 tablets

3N
65841640069

ZyGenerics
NDC 65841-640-06
**risperidONE
ORALLY
DISINTEGRATING**
Tablets
0.5 mg
Rx only
30 Tablets

Each tablet contains:
risperidONE, USP..... 0.5 mg

Phenylketonurics: Contains 1.12 mg phenylalanine (a component of aspartame) per tablet.

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from light and moisture.

Dispense in a tight, light-resistant container.

KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Lot:
Exp:
Rev.: 07/11

NDC 65841-641-06 in bottle of 30 tablets

Risperidone Orally Disintegrating Tablets, 1 mg

Rx only

30 tablets



Lot:
Exp:
Rev.: 07/11

ZyGenerics
NDC 65841-641-06
risperidONE
ORALLY
DISINTEGRATING
Tablets

1 mg
Rx only
30 Tablets

Each tablet contains:
risperidONE, USP..... 1 mg

Phenylketonurics: Contains 2.24 mg phenylalanine (a component of aspartame) per tablet.

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from light and moisture.

Dispense in a tight, light-resistant container.

KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

NDC 65841-642-06 in bottle of 30 tablets
Risperidone Orally Disintegrating Tablets, 2 mg
Rx only
30 tablets



Lot:
Exp:
Rev.: 07/11

ZyGenerics
NDC 65841-642-06
risperidONE
ORALLY
DISINTEGRATING
Tablets

2 mg
Rx only
30 Tablets

Each tablet contains:
risperidONE, USP..... 2 mg

Phenylketonurics: Contains 4.49 mg phenylalanine (a component of aspartame) per tablet.

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from light and moisture.

Dispense in a tight, light-resistant container.

KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

RISPERIDONE

risperidone tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-640	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	RISPERIDONE (UNII: L6UH7ZF8HC) (RISPERIDONE - UNII:L6UH7ZF8HC)	RISPERIDONE	0.5 mg	
Inactive Ingredients				
	Ingredient Name		Strength	
	ASPARTAME (UNII: Z0H242BBR1)			
	CALCIUM STEARATE (UNII: 776XM7047L)			
	CROSPVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)			
	MANNITOL (UNII: 3OWL53L36A)			
	PEPPERMINT (UNII: V95R5KMY2B)			
	SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
	DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)			
Product Characteristics				
Color	WHITE (WHITE TO OFF-WHITE)	Score	no score	
Shape	ROUND (ROUND)	Size	6mm	
Flavor	PEPPERMINT (FLAVOR FIRMENICH POWDER PEPPERMINT)	Imprint Code	ZD;22	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-640-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2010	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA078516	06/29/2010		

RISPERIDONE

risperidone tablet, orally disintegrating

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-641
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RISPERIDONE (UNII: L6UH7ZF8HC) (RISPERIDONE - UNII:L6UH7ZF8HC)	RISPERIDONE	1 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM STEARATE (UNII: 776XM7047L)	
CROSPROVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
MANNITOL (UNII: 3OWL53L36A)	
PEPPERMINT (UNII: V95R5KMY2B)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	8mm
Flavor	PEPPERMINT (FLAVOR FIRMENICH POWDER PEPPERMINT)	Imprint Code	ZD;21
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-641-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078516	06/29/2010	

RISPERIDONE

risperidone tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-642
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
RISPERIDONE (UNII: L6UH7ZF8HC) (RISPERIDONE - UNII:L6UH7ZF8HC)	RISPERIDONE	2 mg

Inactive Ingredients	
Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM STEARATE (UNII: 776XM7047L)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
MANNITOL (UNII: 3OWL53L36A)	
PEPPERMINT (UNII: V95R5KMY2B)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	10mm
Flavor	PEPPERMINT (FLAVOR FIRMENICH POWDER PEPPERMINT)	Imprint Code	ZD;20
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-642-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2010	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078516	06/29/2010	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-640, 65841-641, 65841-642) , MANUFACTURE(65841-640, 65841-641, 65841-642)