

RISPERIDONE- risperidone tablet, film coated
Cadila Healthcare Limited

RISPERIDONE TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Risperidone Tablets USP, 0.25 mg

NDC 65841-665-14

60 tablets

Rx only



Risperidone Tablets USP, 0.5 mg

NDC 65841-666-14

60 tablets

Rx only

No Varnished Area (Do Not Print)
(18 x 41 mm)

NDC 65841-666-14

risperiDONE
Tablets, USP

0.5 mg

Z 6

60 TABLETS
Rx only

zydus
pharmaceuticals

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

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., India

Rev.: 08/18

Risperidone Tablets USP, 1 mg
NDC 65841-667-14
60 Tablets
Rx only

No Varnished Area (Do Not Print)
(18 x 41 mm)

NDC 65841-667-14

risperiDONE
Tablets, USP

1 mg

ZC75

60 TABLETS
Rx only

zydus
pharmaceuticals

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

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., India

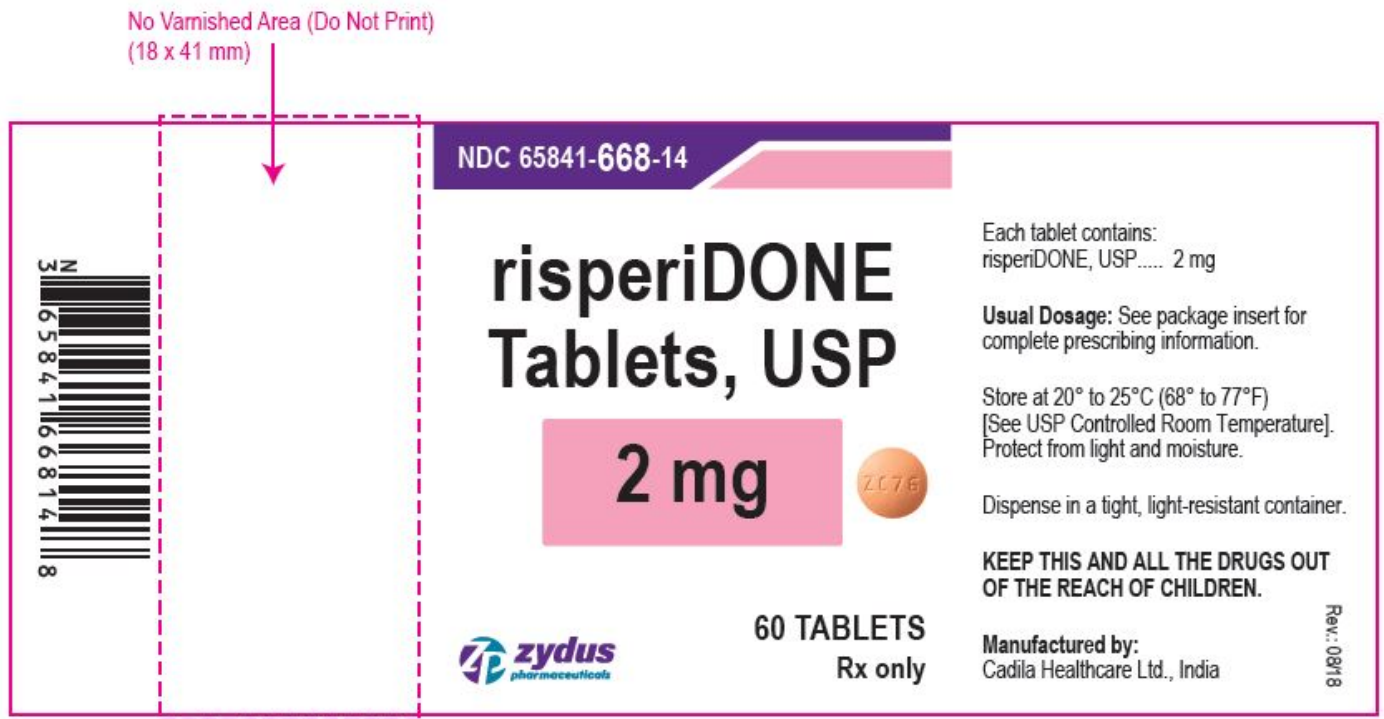
Rev.: 08/18

Risperidone Tablets USP, 2 mg
NDC 65841-668-14

60 Tablets

Rx only

No Varnished Area (Do Not Print)
(18 x 41 mm)



NDC 65841-668-14

risperiDONE
Tablets, USP

2 mg

zydus
pharmaceuticals

60 TABLETS
Rx only

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

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., India

Rev.: 09/18

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Risperidone Tablets USP, 3 mg

NDC 65841-669-14

60 Tablets

Rx only

No Varnished Area (Do Not Print)
(18 x 41 mm)



NDC 65841-669-14

risperiDONE
Tablets, USP

3 mg

zydus
pharmaceuticals

60 TABLETS
Rx only

Each tablet contains:
risperiDONE, USP..... 3 mg

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., India

Rev.: 09/18

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6584166914
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Risperidone Tablets USP, 4 mg

NDC 65841-670-14

60 Tablets

Rx only

No Varnished Area (Do Not Print)
(18 x 41 mm)

NDC 65841-670-14

risperidONE
Tablets, USP

4 mg

60 TABLETS
Rx only

zydus
pharmaceuticals

Each tablet contains:
risperidONE, USP..... 4 mg

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., India

Rev: 08/18

RISPERIDONE

risperidone tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-665
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RISPERIDONE (UNII: L6UH7ZF8HC) (RISPERIDONE - UNII:L6UH7ZF8HC)	RISPERIDONE	0.25 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	YELLOW (DARK YELLOW)	Score	no score
Shape	ROUND (ROUND)	Size	5mm
Flavor		Imprint Code	Z;4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-665-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
2	NDC:65841-665-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
3	NDC:65841-665-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
4	NDC:65841-665-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
5	NDC:65841-665-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
6	NDC:65841-665-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078040	11/13/2008	

RISPERIDONE

risperidone tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-666
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
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	RED (RED BROWN)	Score	no score
Shape	ROUND (ROUND)	Size	5mm
Flavor		Imprint Code	Z;6
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-666-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
2	NDC:65841-666-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
3	NDC:65841-666-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
4	NDC:65841-666-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
5	NDC:65841-666-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
6	NDC:65841-666-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078040	11/13/2008	

RISPERIDONE

risperidone tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-667
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

HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	ZC;75
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-667-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
2	NDC:65841-667-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
3	NDC:65841-667-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
4	NDC:65841-667-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
5	NDC:65841-667-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
6	NDC:65841-667-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078040	11/13/2008	

RISPERIDONE

risperidone tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-668
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
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FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	ORANGE (ORANGE)	Score	no score
Shape	ROUND (ROUND)	Size	8mm
Flavor		Imprint Code	ZC;76
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-668-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
2	NDC:65841-668-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
3	NDC:65841-668-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
4	NDC:65841-668-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
5	NDC:65841-668-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
6	NDC:65841-668-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078040	11/13/2008	

RISPERIDONE

risperidone tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-669
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RISPERIDONE (UNII: L6UH7ZF8HC) (RISPERIDONE - UNII:L6UH7ZF8HC)	RISPERIDONE	3 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	YELLOW (YELLOW)	Score	no score
Shape	ROUND (ROUND)	Size	10mm
Flavor		Imprint Code	ZC;77
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-669-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
2	NDC:65841-669-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
3	NDC:65841-669-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
4	NDC:65841-669-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
5	NDC:65841-669-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
6	NDC:65841-669-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078040	11/12/2008	

RISPERIDONE

risperidone tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-670
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RISPERIDONE (UNII: L6UH7ZF8HC) (RISPERIDONE - UNII:L6UH7ZF8HC)	RISPERIDONE	4 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	GREEN (GREEN)	Score	no score
Shape	ROUND (ROUND)	Size	11mm
Flavor		Imprint Code	ZC;78
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-670-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
2	NDC:65841-670-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
3	NDC:65841-670-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
4	NDC:65841-670-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
5	NDC:65841-670-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	
6	NDC:65841-670-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078040	11/13/2008	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(65841-665, 65841-666, 65841-667, 65841-668, 65841-669, 65841-670), MANUFACTURE(65841-665, 65841-666, 65841-667, 65841-668, 65841-669, 65841-670)

