

PROMETHAZINE HYDROCHLORIDE - promethazine hydrochloride tablet
Zydus Lifesciences Limited

Promethazine Hydrochloride Tablets USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-040-01 in bottle of 100 tablets

Promethazine Hydrochloride Tablets USP, 12.5 mg

R_x only

100 tablets

NDC 65841-040-01

Promethazine Hydrochloride Tablets, USP

12.5 mg

PHARMACIST: Dispense the Patient Information provided separately to each patient.

100 TABLETS
Rx only

Each tablet contains:
Promethazine hydrochloride, USP12.5 mg

Usual Dosage: See package insert for complete prescribing information.

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

Dispense in light-resistant, tight container.

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

Manufactured by:
Cadila Healthcare Ltd., India

Rev: 11/18

NDC 65841-041-01 in bottle of 100 tablets

Promethazine Hydrochloride Tablets USP, 25 mg

R_x only

100 tablets

NDC 65841-041-01

Promethazine Hydrochloride Tablets, USP

25 mg

PHARMACIST: Dispense the Patient Information provided separately to each patient.

zydus pharmaceuticals

100 TABLETS
Rx only

Each tablet contains:
Promethazine hydrochloride, USP 25 mg

Usual Dosage: See package insert for complete prescribing information.

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

Dispense in light-resistant, tight container.

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

Manufactured by:
Cadila Healthcare Ltd., India

Rev: 11/18

NDC 65841-042-01 in bottle of 100 tablets
 Promethazine Hydrochloride Tablets USP, 50 mg
 Rx only
 100 tablets

NDC 65841-042-01

Promethazine Hydrochloride Tablets, USP

50 mg

PHARMACIST: Dispense the Patient Information provided separately to each patient.

zydus pharmaceuticals

100 TABLETS
Rx only

Each tablet contains:
Promethazine hydrochloride, USP50 mg

Usual Dosage: See package insert for complete prescribing information.

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

Dispense in light-resistant, tight container.

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

Manufactured by:
Cadila Healthcare Ltd., India

Rev: 11/18

PROMETHAZINE HYDROCHLORIDE

promethazine hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-040
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PROMETHAZINE HYDROCHLORIDE (UNII: R61ZEH7I1I) (PROMETHAZINE - UNII:FF28EJQ494)	PROMETHAZINE HYDROCHLORIDE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	2 pieces
Shape	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	ZC;01
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-040-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2005	
2	NDC:65841-040-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2005	
3	NDC:65841-040-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040596	12/14/2005	

PROMETHAZINE HYDROCHLORIDE

promethazine hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-041
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PROMETHAZINE HYDROCHLORIDE (UNII: R61ZEH711) (PROMETHAZINE - UNII:FF28EJQ494)	PROMETHAZINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	Score	4 pieces
Shape	ROUND (ROUND)	Size	8mm
Flavor		Imprint Code	Z;C;0;2
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-041-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2005	
2	NDC:65841-041-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2005	
3	NDC:65841-041-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2005	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040596	12/14/2005	

PROMETHAZINE HYDROCHLORIDE

promethazine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-042
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

PROMETHAZINE HYDROCHLORIDE (UNII: R61ZEH711) (PROMETHAZINE - UNII:FF28EJQ494)		PROMETHAZINE HYDROCHLORIDE	50 mg	
Inactive Ingredients				
Ingredient Name			Strength	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)				
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)				
Product Characteristics				
Color	WHITE (WHITE TO OFF-WHITE)	Score	no score	
Shape	ROUND (ROUND)	Size	10mm	
Flavor		Imprint Code	ZC03	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-042-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2005	
2	NDC:65841-042-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2005	
3	NDC:65841-042-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2005	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA040596	12/14/2005		

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-040, 65841-041, 65841-042) , MANUFACTURE(65841-040, 65841-041, 65841-042)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		677605858	ANALYSIS(65841-040, 65841-041, 65841-042) , MANUFACTURE(65841-040, 65841-041, 65841-042)

