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 65841-041-01 in bottle of 100 tablets

Promethazine Hydrochloride Tablets USP, 25 mg

R_x only

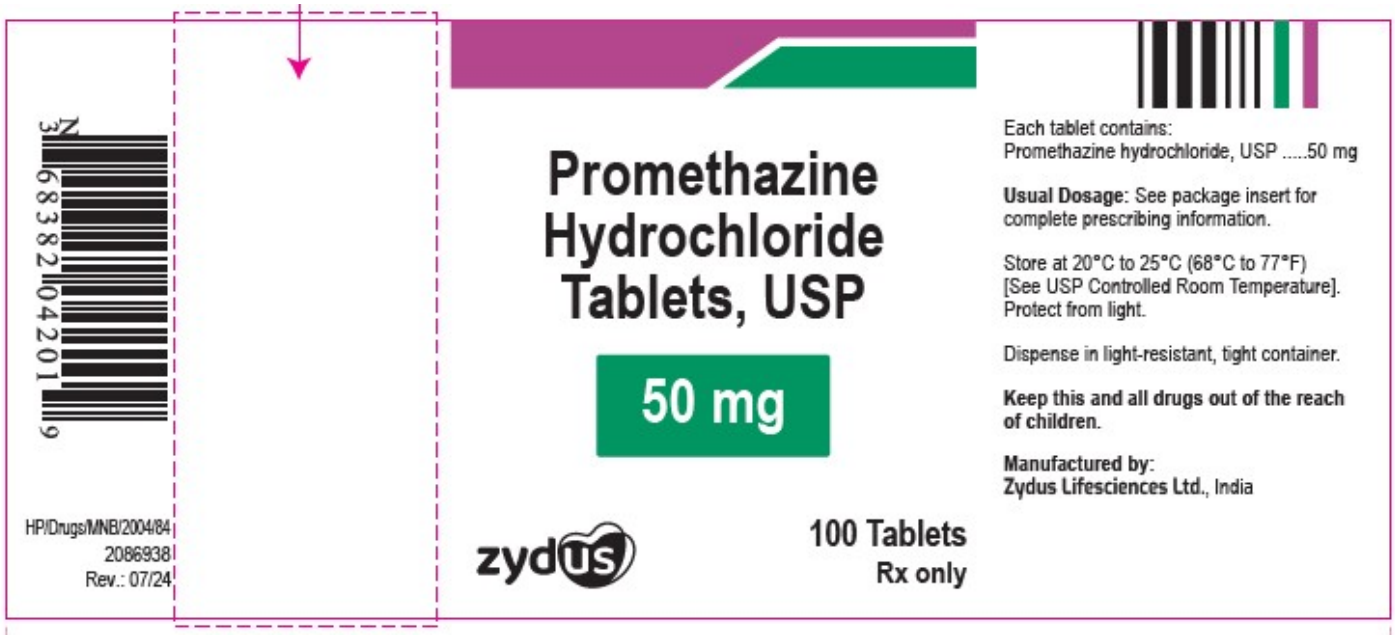
100 tablets

NDC 65841-042-01 in bottle of 100 tablets

Promethazine Hydrochloride Tablets USP, 50 mg

R_x only

100 tablets



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: R61ZEH7I1I) (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: R61ZEH7I1I) (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		677605858	ANALYSIS(65841-040, 65841-041, 65841-042) , MANUFACTURE(65841-040, 65841-041, 65841-042)

Establishment

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

Limited		918596198	65841-041, 65841-042)