

**PROMETHAZINE HYDROCHLORIDE- promethazine hydrochloride tablet**  
**Zydus Lifesciences Limited**

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**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<sub>x</sub> only

100 tablets



NDC 65841-041-01 in bottle of 100 tablets

Promethazine Hydrochloride Tablets USP, 25 mg

R<sub>x</sub> only

100 tablets

**Promethazine Hydrochloride Tablets, USP**

**25 mg**

100 Tablets  
Rx only

Each tablet contains:  
Promethazine hydrochloride, USP ..... 25 mg

**Usual Dosage:** See package insert for complete prescribing information.

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

Dispense in light-resistant, tight container.

**Keep this and all drugs out of the reach of children.**

Manufactured by:  
Zydus Lifesciences Ltd., India

HPIDrugs/MNB/2004/84  
XXXXXXX  
Rev.: 07/24

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

**Promethazine Hydrochloride Tablets, USP**

**50 mg**

100 Tablets  
Rx only

Each tablet contains:  
Promethazine hydrochloride, USP .....50 mg

**Usual Dosage:** See package insert for complete prescribing information.

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

Dispense in light-resistant, tight container.

**Keep this and all drugs out of the reach of children.**

Manufactured by:  
Zydus Lifesciences Ltd., India

HPIDrugs/MNB/2004/84  
2086938  
Rev.: 07/24

## 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: R61ZEH711I) (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
<b>PROMETHAZINE HYDROCHLORIDE</b> (UNII: R61ZEH7I1I) (PROMETHAZINE - UNII:FF28EJQ494)	PROMETHAZINE HYDROCHLORIDE	50 mg

### Inactive Ingredients

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

### Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	ZC03
<b>Contains</b>			

### 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,

Revised: 12/2024

Zydus Lifesciences Limited