

**PROMETHAZINE HYDROCHLORIDE- promethazine hydrochloride tablet  
DIRECT RX**

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**PROMETHAZINE HYDROCHLORIDE 25mg**

**DESCRIPTION**

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**CLINICAL PHARMACOLOGY**

- 

**INDICATIONS AND USAGE**

- 

**CONTRAINDICATIONS**

- 

**WARNINGS**

- 

**PRECAUTIONS**

- 

**ADVERSE REACTIONS**

- 

**OVERDOSAGE**

- 

**DOSAGE AND ADMINISTRATION**

- 

**STORAGE**

- 

**PATIENT INFORMATION LEAFLET**

- 

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

**PROMETHAZINE HYDROCHLORIDE 25mg 60 Tabs**

Generic For: **PHENERGAN**  
Each tablet contains: Promethazine Hydrochloride, USP 25mg

Lot# 630-60 Discard After: 03/17  
Prod# 630-60

Alpharetta, GA 30005

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.  
**RX ONLY-KEEP OUT OF REACH OF CHILDREN**  
Dosage: See package insert. Store between 68-77 degrees F

May cause DROWSINESS. ALCOHOL may INTENSIFY this effect. Use care when operating dangerous machinery.

NDC 61919-630-60

PROMETHAZINE HYDROCHLORIDE NDC 61919-630-60 60 Tab: Lot Exp Date 03/17 Mfg NDC 57664-108-18

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Mfg By: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512 NDC 57664-108-18

Mfg Lot: 2/18/2016

ReVISION

## PROMETHAZINE HYDROCHLORIDE

promethazine hydrochloride tablet

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:61919-630(NDC:57664-108)
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PROMETHAZINE HYDROCHLORIDE (UNII: R61ZEH7111) (PROMETHAZINE - UNII:FF28EJQ494)	PROMETHAZINE HYDROCHLORIDE	25 mg

### Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q815X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6130)	

### Product Characteristics

Color	white (WHITE TO OFF WHITE)	Score	2 pieces
Shape	ROUND	Size	8mm
Flavor		Imprint Code	108
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-630-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/18/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040863	02/18/2016	

**Labeler** - DIRECT RX (079254320)

## Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(61919-630)

Revised: 2/2016

DIRECT RX