PROMETHAZINE HYDROCHLORIDE- promethazine hydrochloride tablet
DIRECT RX

PROMETHAZINE HYDROCHLORIDE 25mg

DESCRIPTION

-

CLINICAL PHARMACOLOGY

-

INDICATIONS AND USAGE

-

CONTRAINDICATIONS

-

WARNINGS

-

PRECAUTIONS

-

ADVERSE REACTIONS

-

OVERDOSAGE

-

DOSAGE AND ADMINISTRATION

-

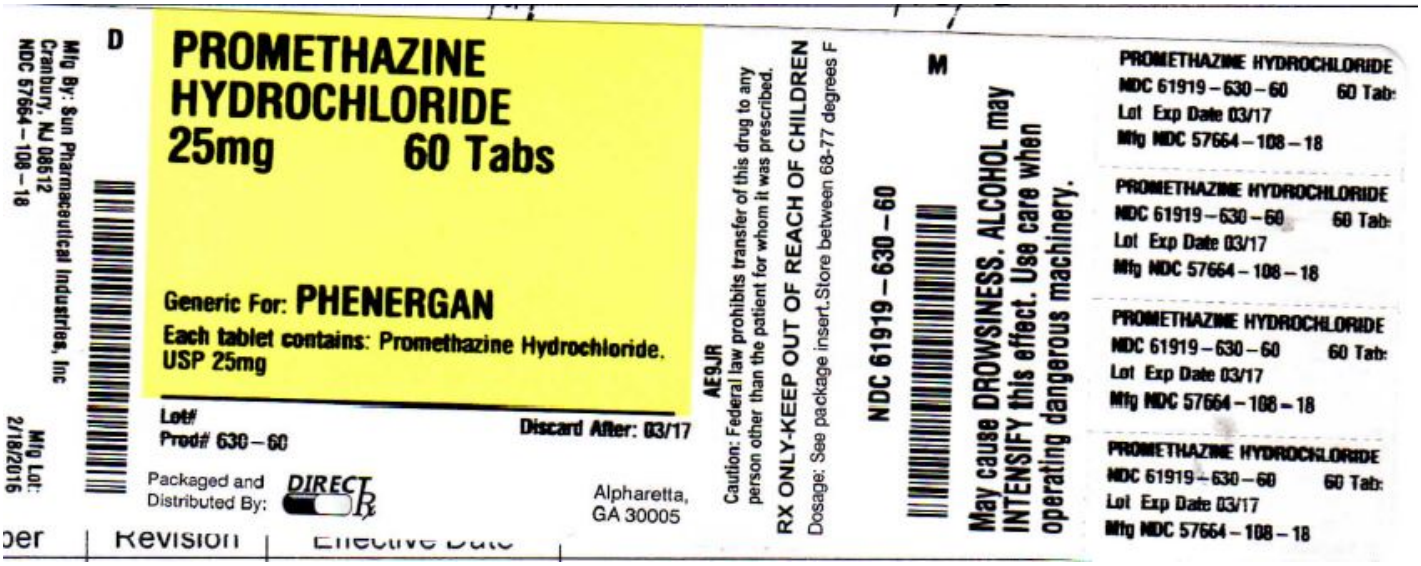
STORAGE

-

PATIENT INFORMATION LEAFLET

-

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



PROMETHAZINE HYDROCHLORIDE

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: R61ZEH7I1I) (PROMETHAZINE - UNII:FF28EJQ494)	PROMETHAZINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

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