PROMETHAZINE HCL- promethazine hcl injection, solution Cantrell Drug Company

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Promethazine HCl 12.5 mg Added to 0.9% Sodium Chloride 25 mL Bag

ProMETHazine Holl 12.5 mg (0.5 mg/mL)*

0.9% Sodium Chloride 25 mL* Bag

Note Dose:

12.5 mg

NDC: 52533-177-78



(01) 0 0352533 17778 1

Rx Only

Store Refrigerated. Protect from Light. Single-Dose Bag. Hospital/Office Use Only. Injection Solution For IV Use.

*Each mL Contains: Promethazine HCl 0.5 mg, Sodium Cl 9 mg, EDTA 1 mcg, Calcium Cl 0.4 mcg, Sodium Metabisulfite 2.5 mcg and Phenol 0.05 mg. pH adjusted with Acetic Acid/Sodium Acetate.

*Volume & Concentration Excludes Manufacturer Overfill

Outsourced Compounded Drug. Not for Resale.

Lot: xxxxx

BUD:

CMPD Date: 03/13

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CANTRELL DRUG COMPANY
7321 Cantrell Road Little Rock, AR 72207
(877) 666-5222 www.cantrelldrug.com

PROMETHAZINE HCL

promethazine hcl injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52533-177
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PROMETHAZINE HYDRO CHLO RIDE (UNII: R6 1ZEH7I1I) (PROMETHAZINE - UNII:FF28 EJQ494)	PROMETHAZINE HYDROCHLORIDE	0.5 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
SODIUM CHLORIDE (UNII: 451W47IQ8X)	9 mg in 1 mL		
EDETATE SO DIUM (UNII: MP1J8420LU)	$0.025 \ \text{mg} \ \text{in} \ 1 \ \text{mL}$		
CALCIUM CHLO RIDE (UNII: M4I0 D6 VV5M)	0.01 mg in 1 mL		
SO DIUM METABISULFITE (UNII: 4VON5FNS3C)	0.0625 mg in 1 mL		
PHENOL (UNII: 339 NCG44TV)	1.25 mg in 1 mL		
WATER (UNII: 059QF0KO0R)			

Other Ingredients			
Ingredient Kind	Ingredient Name	Quantity	
May contain	ACETIC ACID (UNII: Q40Q9N063P)		
May contain	SODIUM ACETATE (UNII: 4550K0SC9B)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:52533-177-78	25 mL in 1 BAG		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/29/2014	

Labeler - Cantrell Drug Company (035545763)

Revised: 8/2014 Cantrell Drug Company