CHLORPROMAZINE HYDROCHLORIDE- chlorpromazine hydrochloride injection
Zydus Lifesciences Limited

Chlorpromazine Hydrochloride Injection, USP

SPL UNCLASSIFIED

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1778-1

chlorproMAZINE Hydrochloride Injection, USP

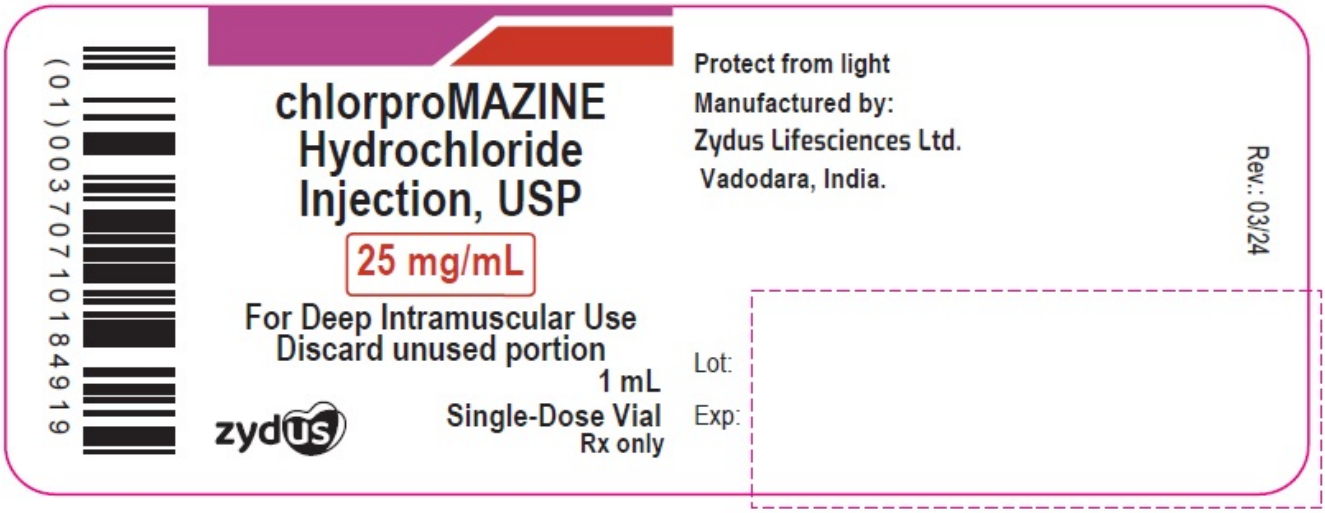
25 mg/mL

For Deep Intramuscular Use

Discard unused portion

1 mL Single-Dose Vial

Rx only



NDC 70771-1778-7

chlorproMAZINE Hydrochloride Injection, USP

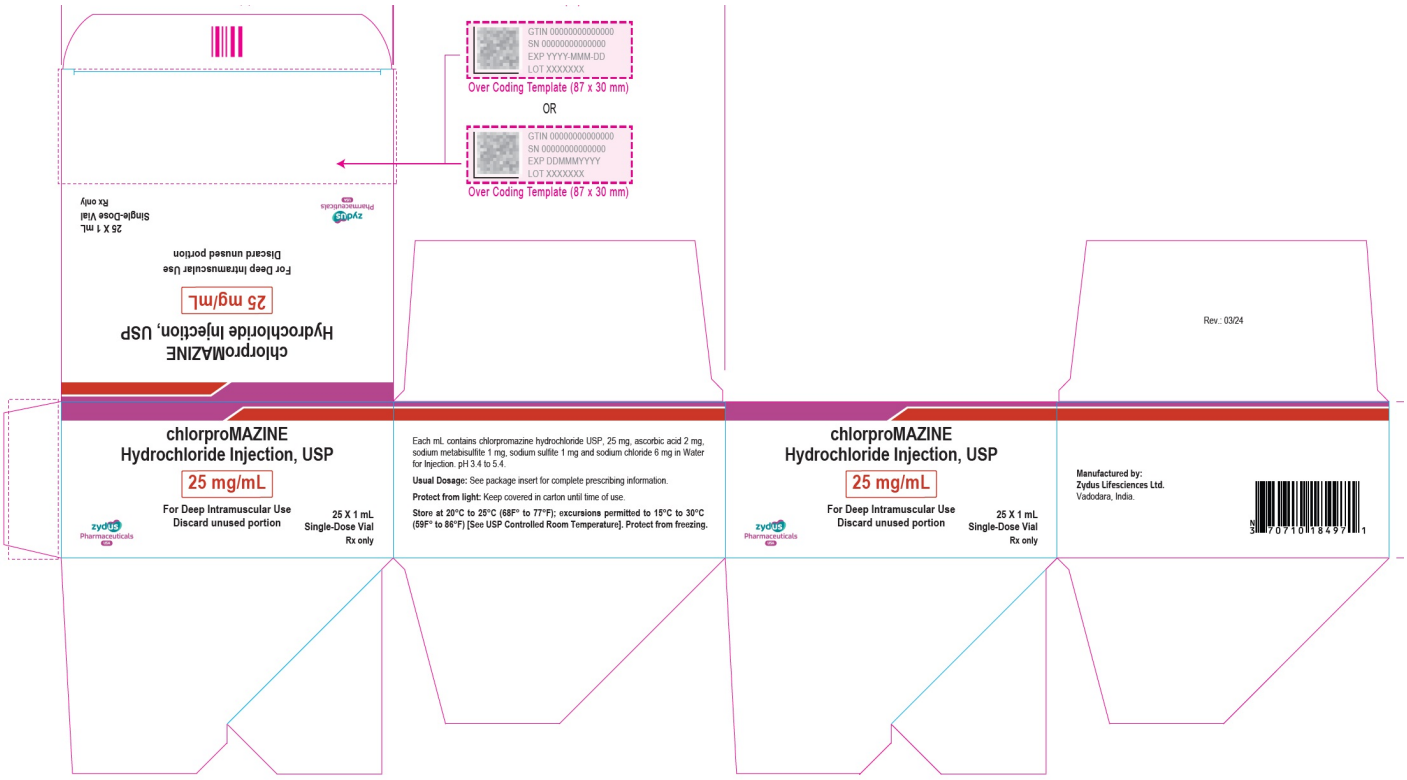
25 mg/mL

For Deep Intramuscular Use

Discard unused portion

25 x 1 mL Single-Dose Vial

Rx only



CHLORPROMAZINE HYDROCHLORIDE

chlorpromazine hydrochloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1779
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPROMAZINE HYDROCHLORIDE (UNII: 9WP59609J6) (CHLORPROMAZINE - UNII:U42B7VYA4P)	CHLORPROMAZINE HYDROCHLORIDE	25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R)	2 mg in 1 mL
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	1 mg in 1 mL
SODIUM SULFITE (UNII: VTK01UQK3G)	1 mg in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	6 mg in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging

			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1779-7	25 in 1 CARTON	03/29/2024	
1	NDC:70771-1779-1	2 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217275	03/29/2024	

CHLORPROMAZINE HYDROCHLORIDE

chlorpromazine hydrochloride injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1778
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPROMAZINE HYDROCHLORIDE (UNII: 9WP59609J6) (CHLORPROMAZINE - UNII:U42B7VYA4P)	CHLORPROMAZINE HYDROCHLORIDE	25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R)	2 mg in 1 mL
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	1 mg in 1 mL
SODIUM SULFITE (UNII: VTK01UQK3G)	1 mg in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	6 mg in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1778-7	25 in 1 CARTON	03/29/2024	
1	NDC:70771-1778-1	1 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA217275	03/29/2024	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Pharmaceuticals USA Inc. (156861945)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		873671928	MANUFACTURE(70771-1778, 70771-1779) , ANALYSIS(70771-1778, 70771-1779)

Revised: 3/2024 Zydus Lifesciences Limited