CHLORPROMAZINE HYDROCHLORIDE- chlorpromazine hydrochloride tablet, film coated
Zydus Lifesciences Limited

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chlorproMAZINE Hydrochloride Tablets, USP

Rx only

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

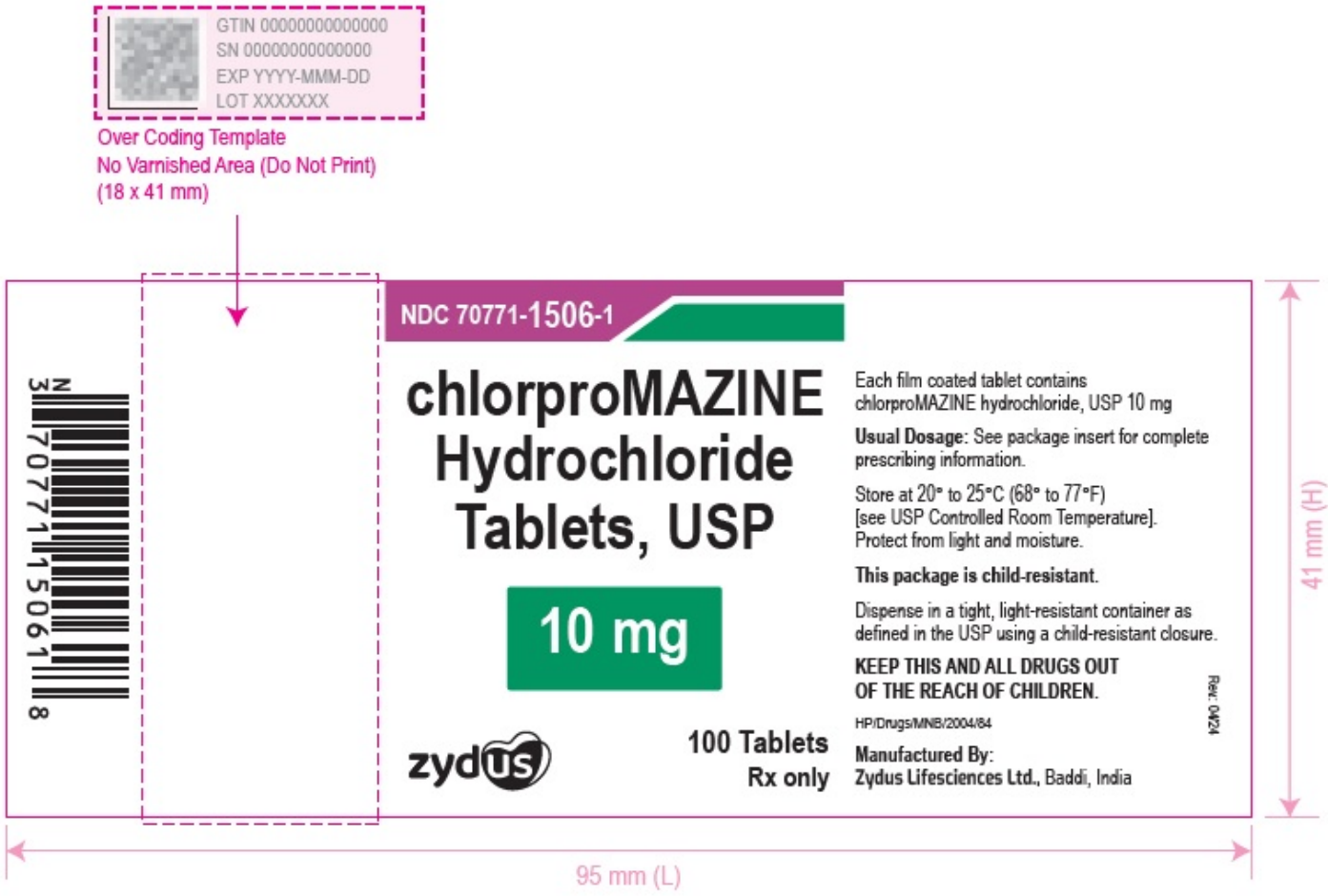
NDC 70771-1506-1

chlorproMAZINE Hydrochloride Tablets, USP

10 mg

100 Tablets

Rx only



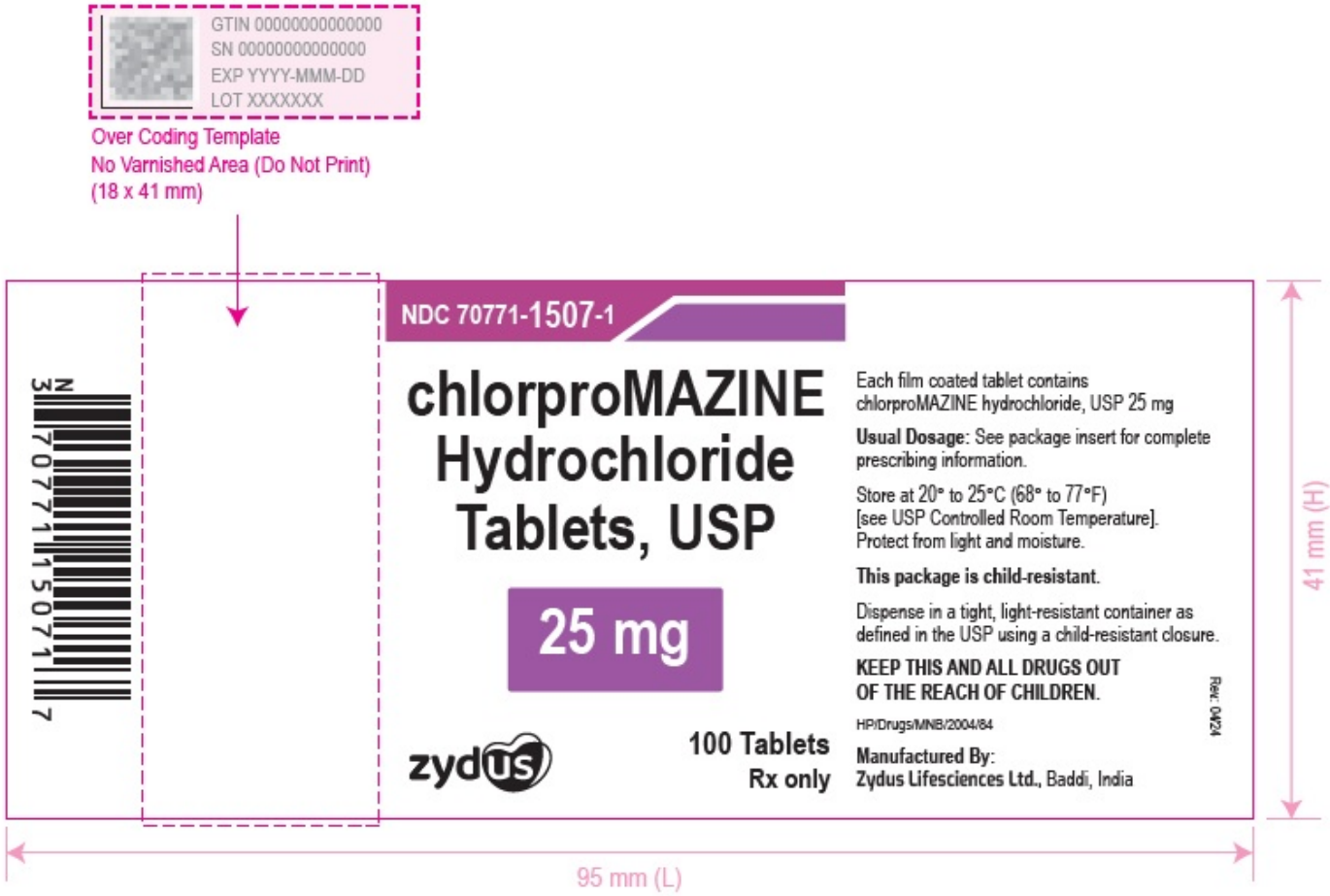
NDC 70771-1507-1

chlorproMAZINE Hydrochloride Tablets, USP

25 mg

100 Tablets

Rx only



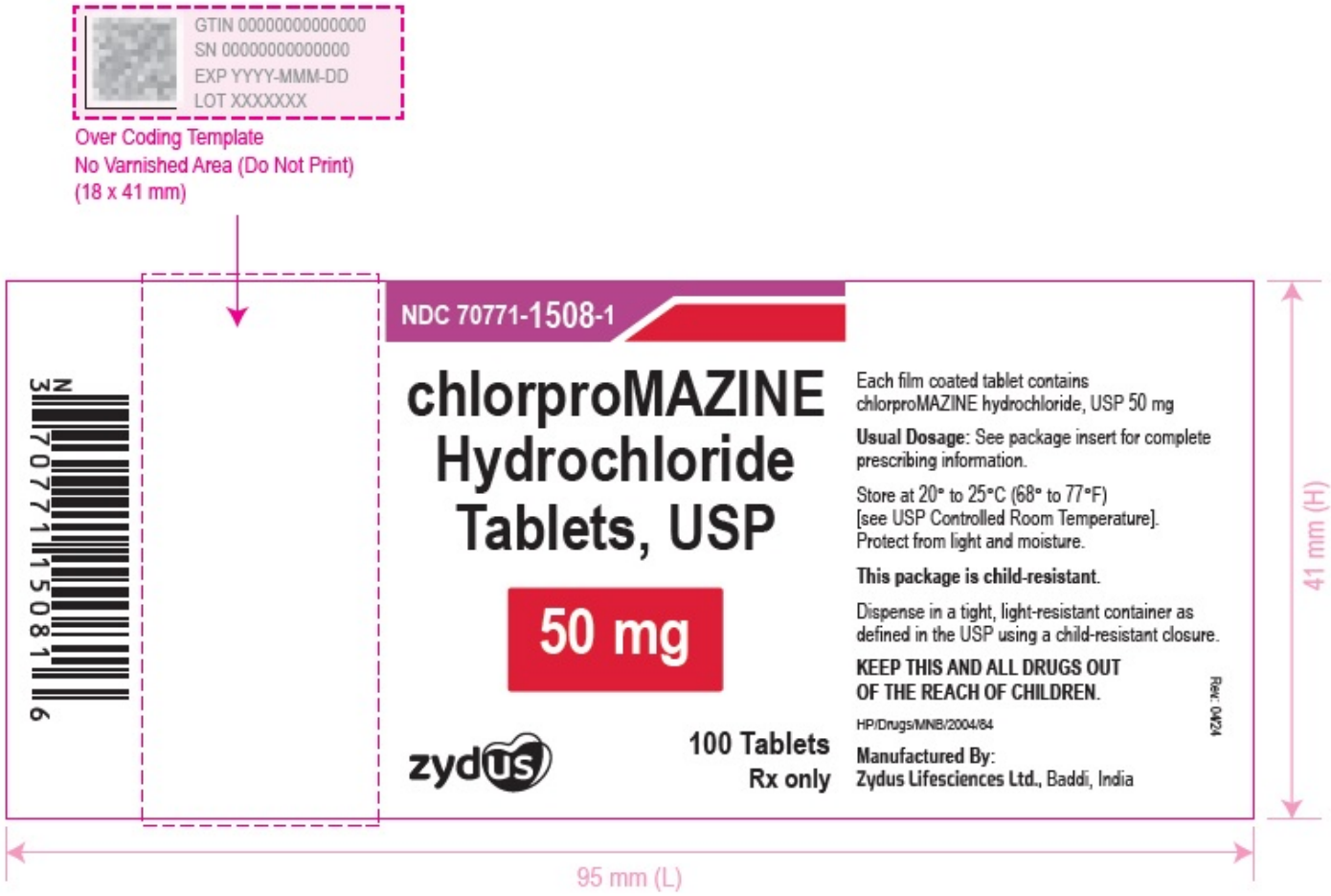
NDC 70771-1508-1

chlorproMAZINE Hydrochloride Tablets, USP

50 mg

100 Tablets

Rx only



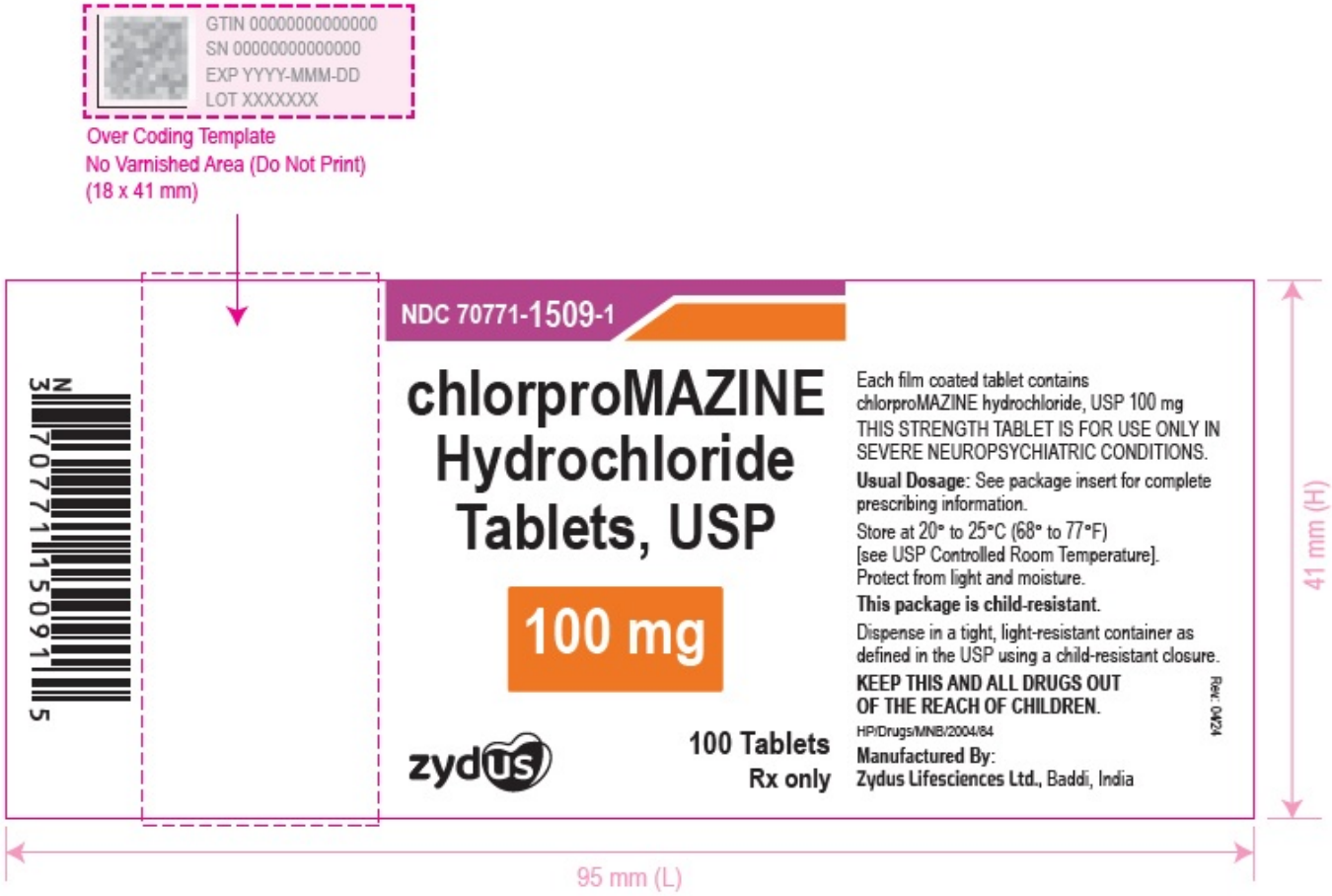
NDC 70771-1509-1

chlorproMAZINE Hydrochloride Tablets, USP

100 mg

100 Tablets

Rx only



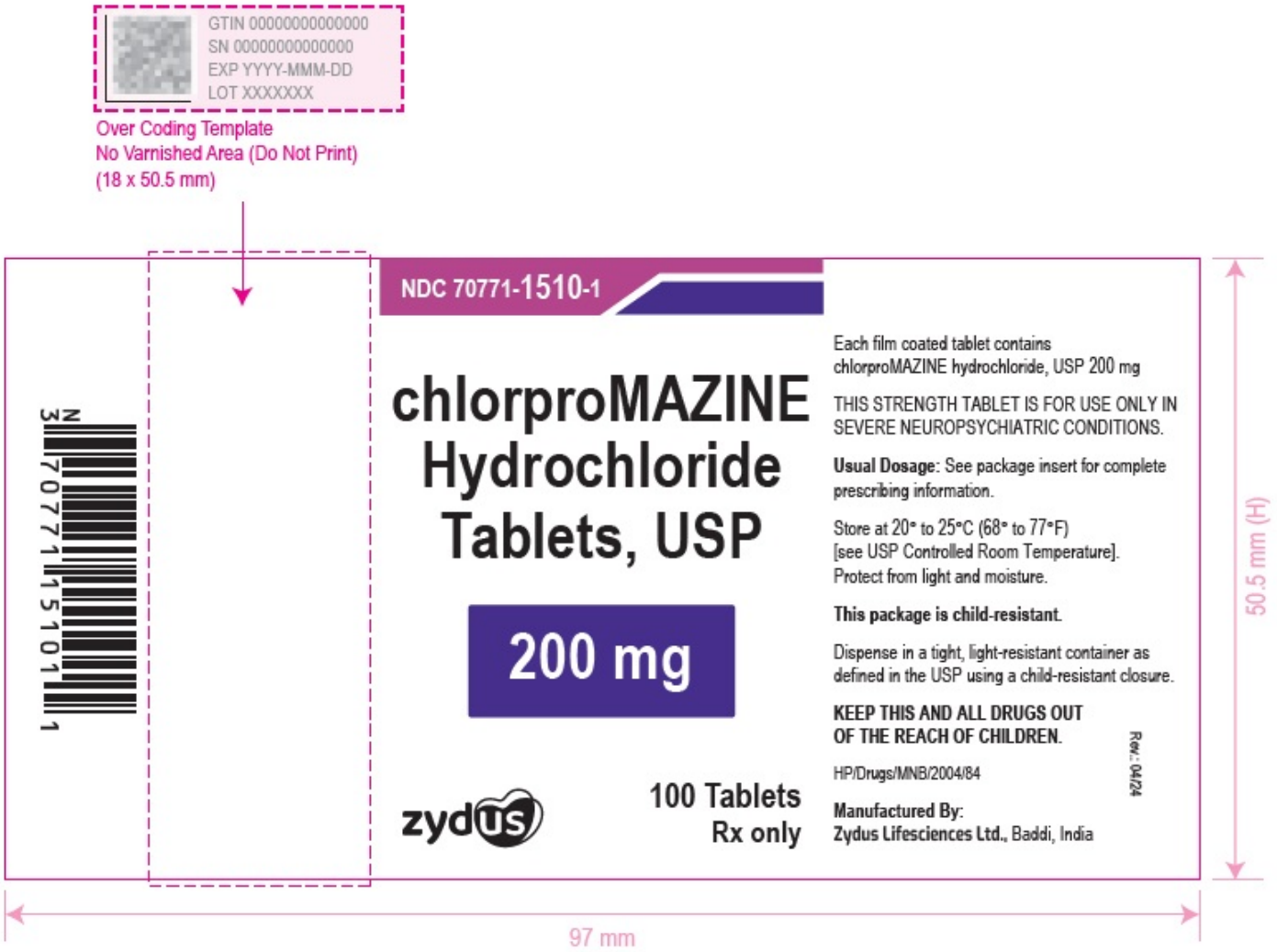
NDC 70771-1510-1

chlorproMAZINE Hydrochloride Tablets, USP

200 mg

100 Tablets

Rx only



CHLORPROMAZINE HYDROCHLORIDE

chlorpromazine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1506
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLORPROMAZINE HYDROCHLORIDE (UNII: 9WP59609J6) (CHLORPROMAZINE - UNII:U42B7VYA4P)	CHLORPROMAZINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM SULFATE DIHYDRATE (UNII: 4846Q921YM)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BROWN	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	11;29
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1506-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2020	
2	NDC:70771-1506-4	10 in 1 CARTON	01/27/2020	
2	NDC:70771-1506-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213368	01/27/2020	

CHLORPROMAZINE HYDROCHLORIDE

chlorpromazine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1507
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM SULFATE DIHYDRATE (UNII: 4846Q921YM)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BROWN	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	11;30
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1507-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2020	
2	NDC:70771-1507-4	10 in 1 CARTON	01/27/2020	
2	NDC:70771-1507-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213368	01/27/2020	

CHLORPROMAZINE HYDROCHLORIDE

chlorpromazine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1508

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPROMAZINE HYDROCHLORIDE (UNII: 9WP59609J6) (CHLORPROMAZINE - UNII:U42B7VYA4P)	CHLORPROMAZINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM SULFATE DIHYDRATE (UNII: 4846Q921YM)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BROWN	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	11;31
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1508-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2020	
2	NDC:70771-1508-4	10 in 1 CARTON	01/27/2020	
2	NDC:70771-1508-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213368	01/27/2020	

CHLORPROMAZINE HYDROCHLORIDE

chlorpromazine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1509
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPROMAZINE HYDROCHLORIDE (UNII: 9WP59609J6) (CHLORPROMAZINE - UNII:U42B7VYA4P)	CHLORPROMAZINE HYDROCHLORIDE	100 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM SULFATE DIHYDRATE (UNII: 4846Q921YM)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BROWN	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	11;32
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1509-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2020	
2	NDC:70771-1509-4	10 in 1 CARTON	01/27/2020	
3	NDC:70771-	10 in 1 BLISTER PACK; Type 0: Not a Combination		

2	1509-2	Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213368	01/27/2020	

CHLORPROMAZINE HYDROCHLORIDE

chlorpromazine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1510
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPROMAZINE HYDROCHLORIDE (UNII: 9WP59609J6) (CHLORPROMAZINE - UNII:U42B7VYA4P)	CHLORPROMAZINE HYDROCHLORIDE	200 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM SULFATE DIHYDRATE (UNII: 4846Q921YM)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BROWN	**Score**	no score
Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	11;33
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1510-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2020	
2	NDC:70771-1510-4	10 in 1 CARTON	01/27/2020	
2	NDC:70771-1510-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213368	01/27/2020	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (677605858)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		677605858	ANALYSIS(70771-1506, 70771-1507, 70771-1508, 70771-1509, 70771-1510) , MANUFACTURE(70771-1506, 70771-1507, 70771-1508, 70771-1509, 70771-1510)

Revised: 6/2024 Zydus Lifesciences Limited