CLOMIPRAMINE HYDROCHLORIDE- clomipramine hydrochloride capsule
Zydus Lifesciences Limited

Clomipramine Hydrochloride Capsules, USP

SPL MEDGUIDE

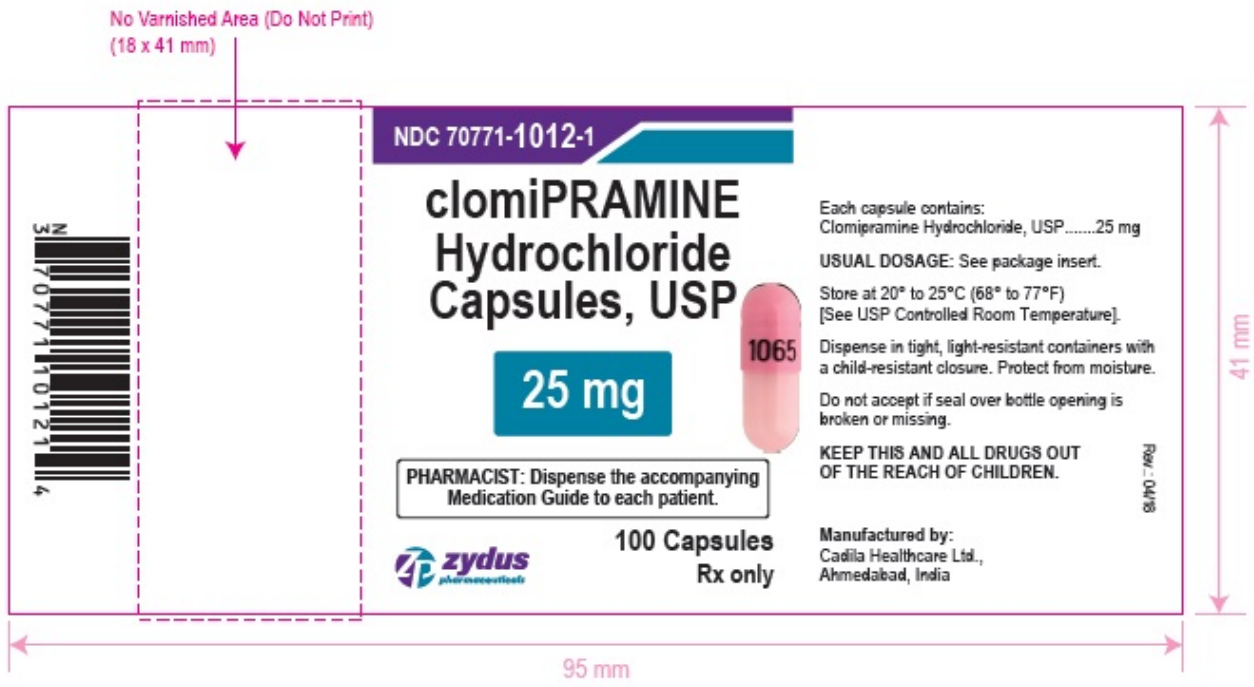
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1012-1

Clomipramine Hydrochloride Capsules USP, 25 mg

R_x only

100 Capsules



NDC 70771-1013-1

Clomipramine Hydrochloride Capsules USP, 50 mg

R_x only

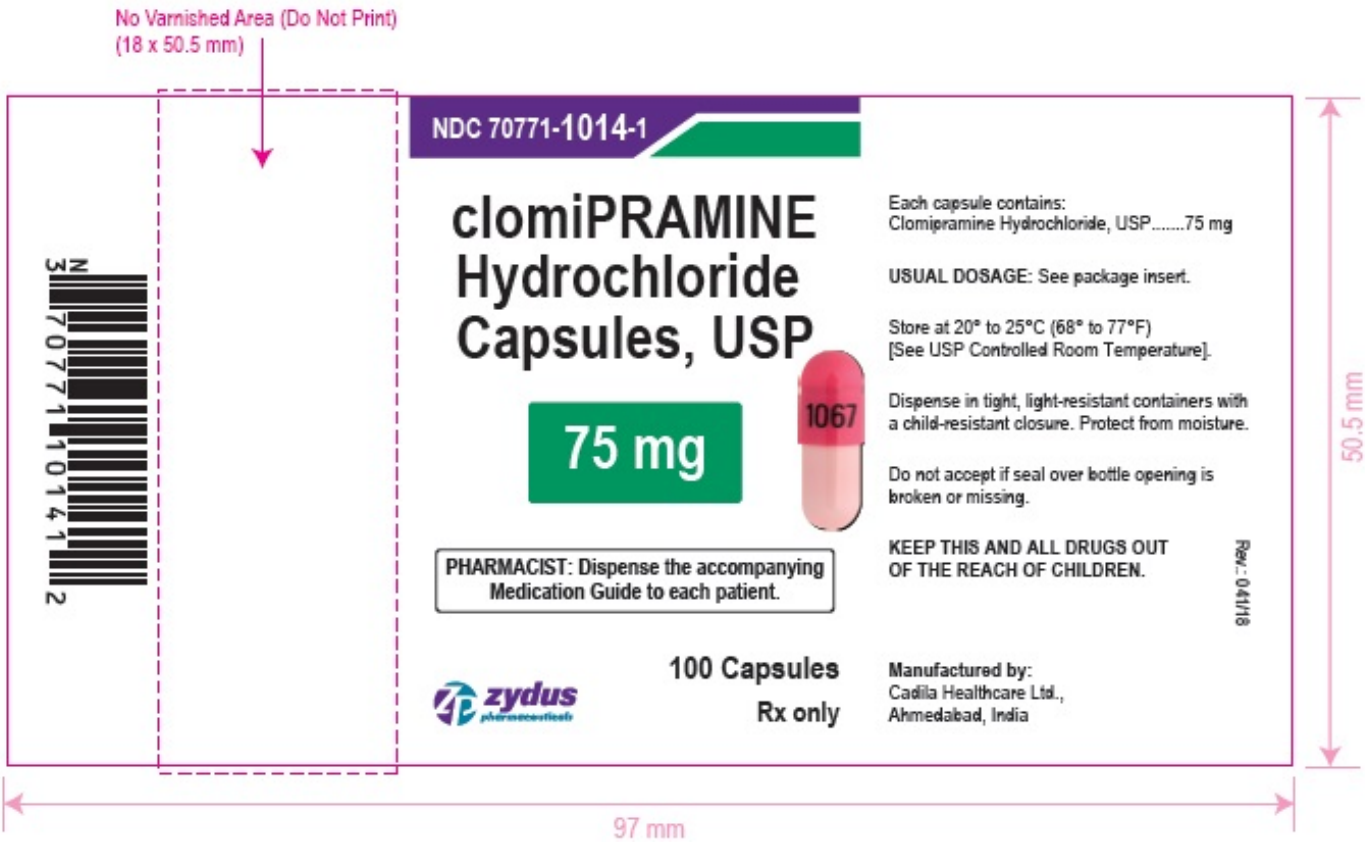
100 Capsules

NDC 70771-1014-1

Clomipramine Hydrochloride Capsules USP, 75 mg

R_x only

100 Capsules



CLOMIPRAMINE HYDROCHLORIDE

clomipramine hydrochloride capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1012
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CLOMIPRAMINE HYDROCHLORIDE (UNII: 2LXW0L6GWJ) (CLOMIPRAMINE - UNII:NUV44L116D)	CLOMIPRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	PINK (OPAQUE PINK CAP) , PINK (OPAQUE LIGHT PINK BODY)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	18mm
Flavor		**Imprint Code**	1065
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1012-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2018	
2	NDC:70771-1012-7	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2018	
3	NDC:70771-1012-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208961	05/03/2018	

CLOMIPRAMINE HYDROCHLORIDE

clomipramine hydrochloride capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1013
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOMIPRAMINE HYDROCHLORIDE (UNII: 2LXW0L6GWJ) (CLOMIPRAMINE - UNII:NUV44L116D)	CLOMIPRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	YELLOW (OPAQUE YELLOW CAP) , PINK (OPAQUE LIGHT PINK BODY)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	19mm
Flavor		**Imprint Code**	1066
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1013-7	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2018	
2	NDC:70771-1013-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2018	
3	NDC:70771-1013-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208961	05/03/2018	

CLOMIPRAMINE HYDROCHLORIDE

clomipramine hydrochloride capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1014
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CLOMIPRAMINE HYDROCHLORIDE (UNII: 2LXW0L6GWJ) (CLOMIPRAMINE - UNII:NUV44L116D)	CLOMIPRAMINE HYDROCHLORIDE	75 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	PINK (OPAQUE DARK PINK CAP) , PINK (OPAQUE LIGHT PINK BODY)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	19mm
Flavor		**Imprint Code**	1067
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1014-7	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2018	
2	NDC:70771-1014-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2018	
3	NDC:70771-1014-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/03/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208961	05/03/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1012, 70771-1013, 70771-1014) , MANUFACTURE(70771-1012, 70771-1013, 70771-1014)

Revised: 9/2023 Zydus Lifesciences Limited