

DOXEPIN HYDROCHLORIDE- doxepin hydrochloride capsule
Zydus Lifesciences Limited

Doxepin Hydrochloride Capsules, USP

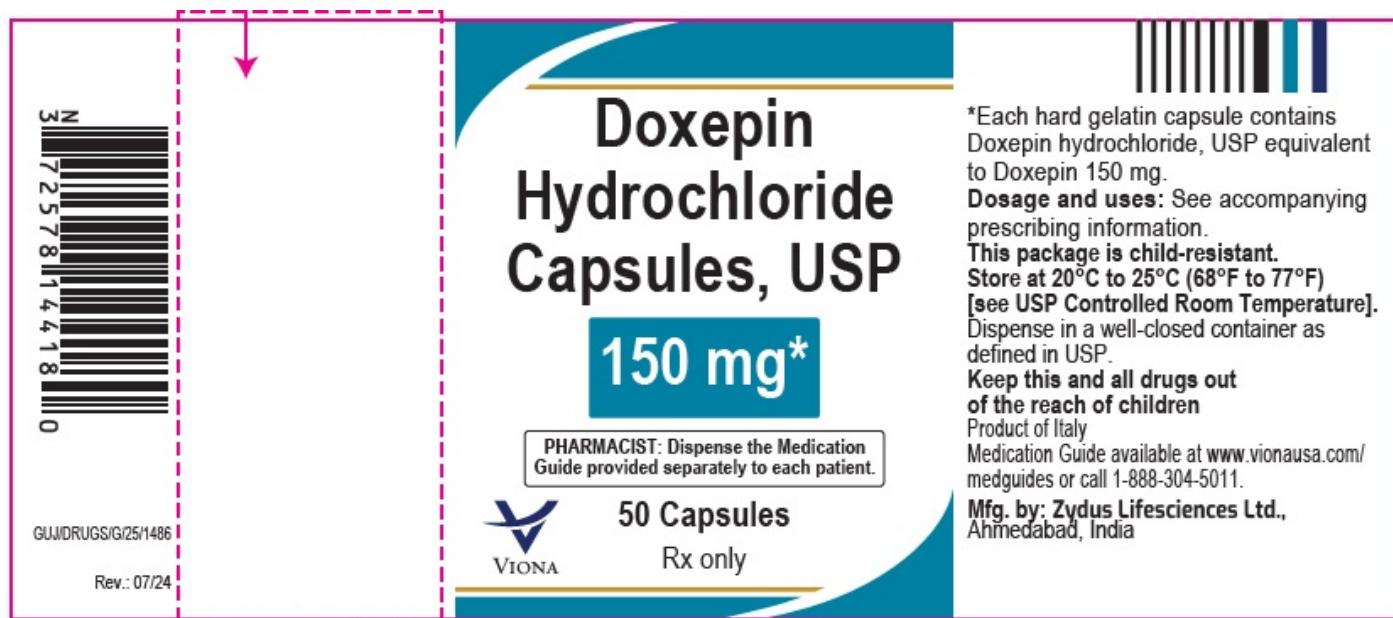
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1390-7

Doxepin Hydrochloride Capsules USP, 150 mg

Rx only

50 Capsules



DOXEPIN HYDROCHLORIDE

doxepin hydrochloride capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1390
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXEPIN HYDROCHLORIDE (UNII: 3U9A0FE9N5) (DOXEPIN - UNII:5ASJ6HUZ7D)	DOXEPIN	150 mg

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERROSFERRIC 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	WHITE (OPAQUE WHITE BODY) , BLUE (OPAQUE BLUE CAP)	Score	no score
Shape	CAPSULE	Size	21mm
Flavor		Imprint Code	1301
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1390-7	50 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	
2	NDC:70771-1390-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	
3	NDC:70771-1390-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	
4	NDC:70771-1390-4	10 in 1 CARTON	03/01/2024	
4	NDC:70771-1390-2	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	ANDA210140	03/01/2024	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1390) , MANUFACTURE(70771-1390)

Revised: 7/2024

Zydus Lifesciences Limited