DOXEPIN- doxepin tablet
Zydus Lifesciences Limited

DOXEPIN tablets, for oral use

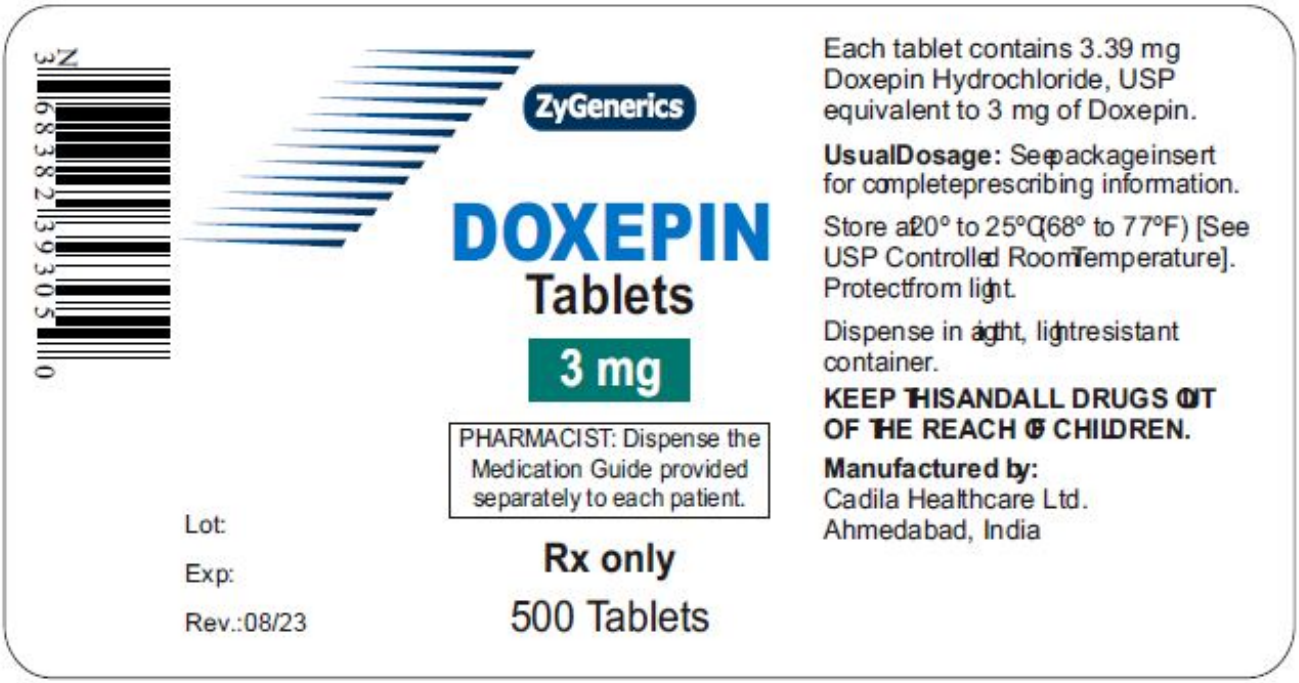
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1528-5 in bottle of 500 tablets

Doxepin Tablets, 3 mg

Rx only

500 tablets

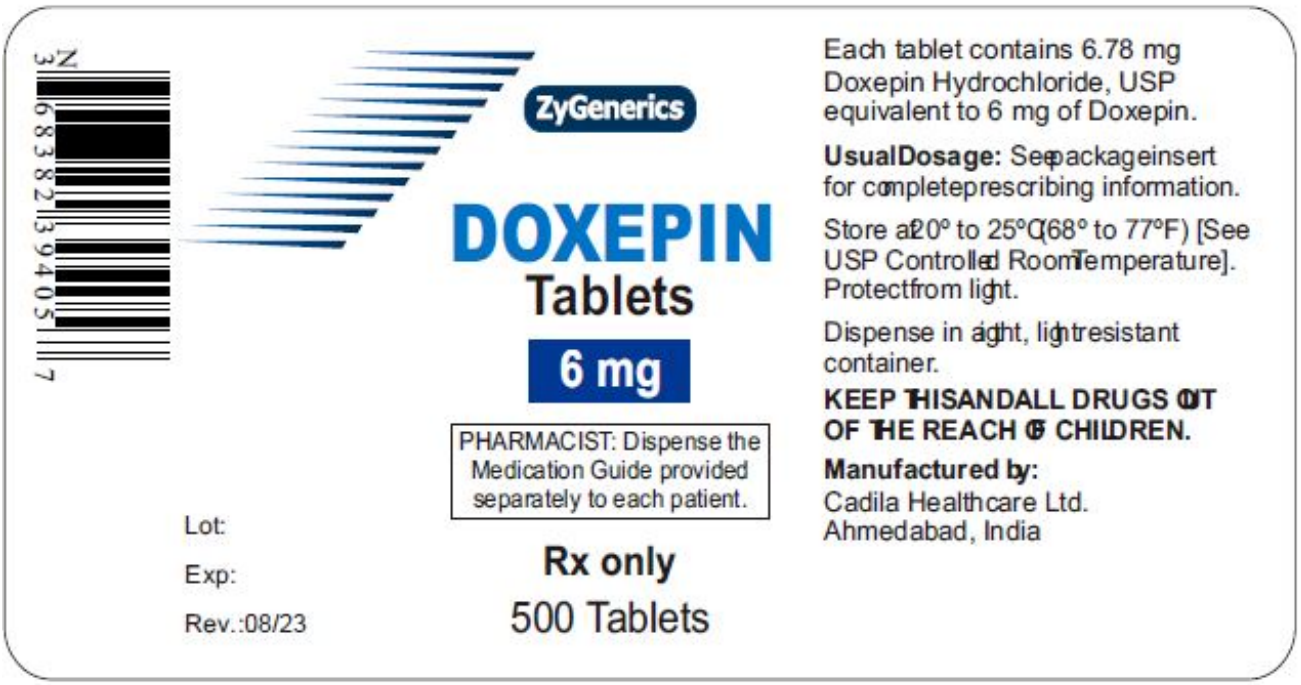


NDC 70771-1529-5 in bottle of 500 tablets

Doxepin Tablets, 6 mg

Rx only

500 tablets



DOXEPIN

doxepin tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1528
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOXEPIN HYDROCHLORIDE (UNII: 3U9A0FE9N5) (DOXEPIN - UNII:5ASJ6HUZ7D)	DOXEPIN	3 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	BLUE (LIGHT BLUE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	6mm
Flavor		**Imprint Code**	393

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1528-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/25/2023	
2	NDC:70771-1528-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/25/2023	
3	NDC:70771-1528-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/25/2023	
4	NDC:70771-1528-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/25/2023	
5	NDC:70771-1528-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/25/2023	
6	NDC:70771-1528-4	10 in 1 CARTON	08/25/2023	
6		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	ANDA202761	08/25/2023	

DOXEPIN

doxepin tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1529
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXEPIN HYDROCHLORIDE (UNII: 3U9A0FE9N5) (DOXEPIN - UNII:5ASJ6HUZ7D)	DOXEPIN	6 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	GREEN (LIGHT GREEN)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	6mm
Flavor		**Imprint Code**	394
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1529-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/25/2023	
2	NDC:70771-1529-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/25/2023	
3	NDC:70771-1529-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/25/2023	
4	NDC:70771-1529-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/25/2023	
5	NDC:70771-1529-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/25/2023	
6	NDC:70771-1529-4	10 in 1 CARTON	08/25/2023	
6		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	ANDA202761	08/25/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1528, 70771-1529) , MANUFACTURE(70771-1528, 70771-1529)

Revised: 9/2023 Zydus Lifesciences Limited