DESMOPRESSIN ACETATE - desmopressin acetate spray
Zydus Lifesciences Limited

DESMOPRESSIN ACETATE NASAL SOLUTION (NASAL SPRAY)

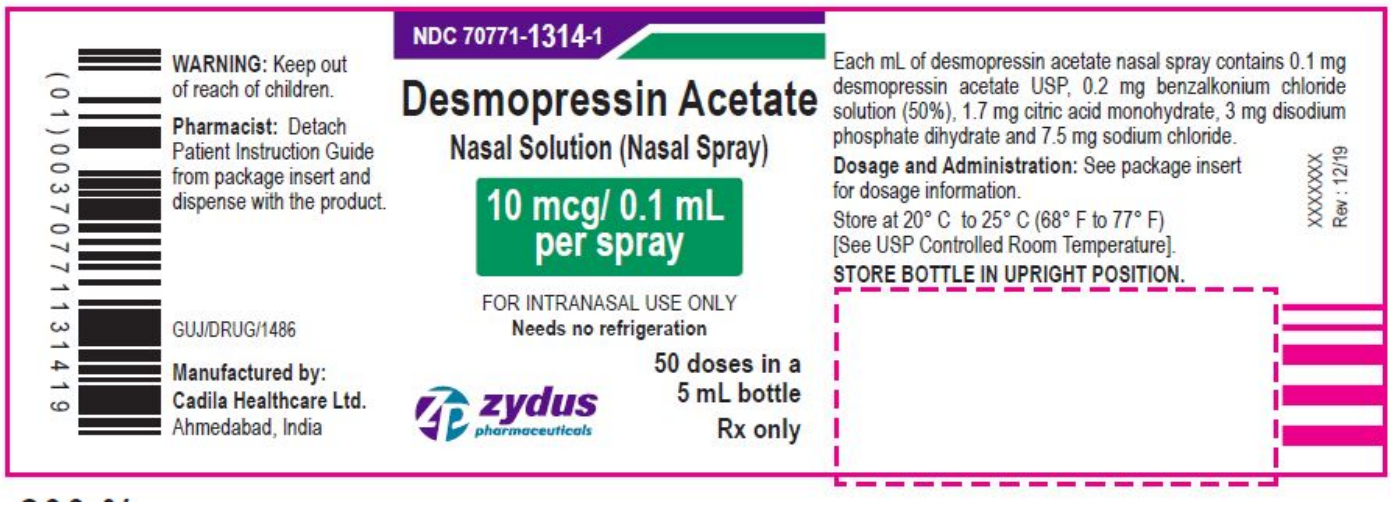
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1314-1

Desmopressin Acetate Nasal Solution (Nasal Spray), 10 mcg/ 0.1 mL per spray

5 mL

Rx only



DESMOPRESSIN ACETATE

desmopressin acetate spray

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1314
Route of Administration	NASAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DESMOPRESSIN ACETATE (UNII: XB13HYU18U) (DESMOPRESSIN - UNII:ENR1LLB0FP)	DESMOPRESSIN ACETATE	0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**

SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1314-1	5 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091345	02/01/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1314) , MANUFACTURE(70771-1314)

Revised: 10/2022 Zydus Lifesciences Limited