

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

NDC 70771-1314-1

Desmopressin Acetate
Nasal Solution (Nasal Spray)

10 mcg/ 0.1 mL
per spray

FOR INTRANASAL USE ONLY
 Needs no refrigeration

50 doses in a
 5 mL bottle
 Rx only

z y d u s
 pharmaceuticals

WARNING: Keep out of reach of children.

Pharmacist: Detach Patient Instruction Guide from package insert and dispense with the product.

Each mL of desmopressin acetate nasal spray contains 0.1 mg desmopressin acetate USP, 0.2 mg benzalkonium chloride solution (50%), 1.7 mg citric acid monohydrate, 3 mg disodium phosphate dihydrate and 7.5 mg sodium chloride.

Dosage and Administration: See package insert for dosage information.

Store at 20° C to 25° C (68° F to 77° F)
 [See USP Controlled Room Temperature].

STORE BOTTLE IN UPRIGHT POSITION.

XXXXXXXX
 Rev : 12/19

(01)00370771131419

GUJ/DRUG/1486

Manufactured by:
 Cadila Healthcare Ltd.
 Ahmedabad, India

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
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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