

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

WARNING: Keep out of reach of children.
Pharmacist: Detach Patient Instruction Guide from package insert and dispense with the product.
 GUJ/DRUGS/G/25/1486
Manufactured by:
 Zydus Lifesciences Ltd.
 Ahmedabad, India

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

FOR INTRANASAL USE ONLY
 Needs no refrigeration

zydus

50 doses in a
 5 mL bottle
 Rx only

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.

2089398
 Rev.: 07/24

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: 7/2024

Zydus Lifesciences Limited