AZELASTINE HYDROCHLORIDE - azelastine hydrochloride spray, metered
Zydus Lifesciences Limited

AZELASTINE hydrochloride nasal solution (nasal spray), 137 mcg

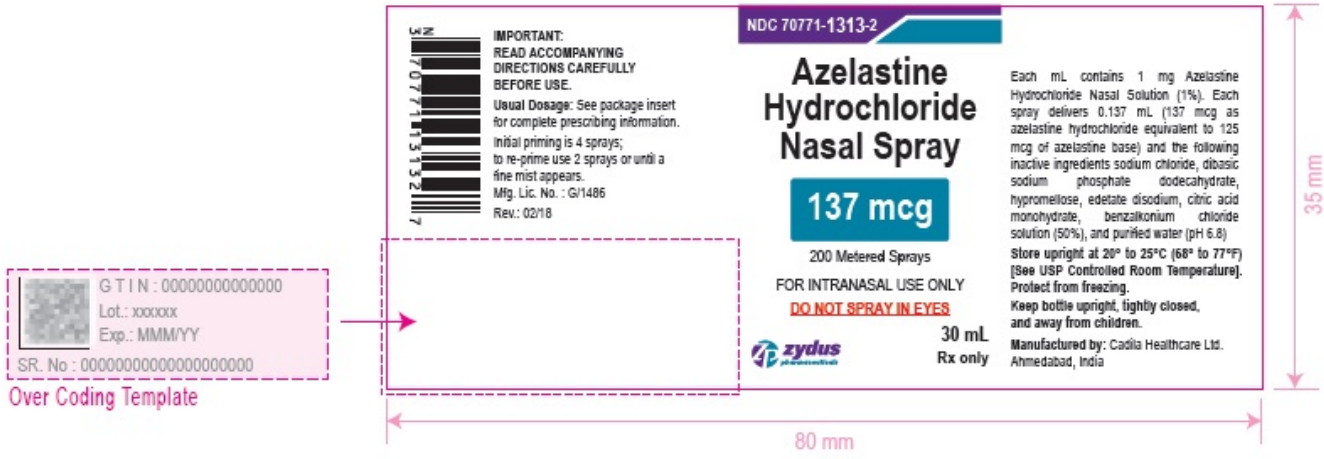
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1313-2

Azelastine Hydrochloride Nasal Spray, 137 mcg per spray

30 mL

Rx only



AZELASTINE HYDROCHLORIDE

azelastine hydrochloride spray, metered

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1313
Route of Administration	NASAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AZELASTINE HYDROCHLORIDE (UNII: 0L591QR10I) (AZELASTINE - UNII:ZQI909440X)	AZELASTINE HYDROCHLORIDE	137 ug

Inactive Ingredients	
Ingredient Name	**Strength**

SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, DIBASIC, DODECAHYDRATE (UNII: E1W4N241FO)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1313-2	1 in 1 CARTON	02/01/2018	
1		200 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091409	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(70771-1313) , MANUFACTURE(70771-1313)

Revised: 10/2022 Zydus Lifesciences Limited