

**DEXMEDETOMIDINE HYDROCHLORIDE - dexmedetomidine hydrochloride injection, solution, concentrate**  
**Zydus Lifesciences Limited**

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**DEXMEDETOMIDINE HYDROCHLORIDE INJECTION**

**PRINCIPAL DISPLAY PANEL**

**200 MCG/2 ML CONTAINER LABEL**

NDC 70771-1319-1

Dexmedetomidine

Hydrochloride Injection

200 mcg/2 mL

(100 mcg/mL)

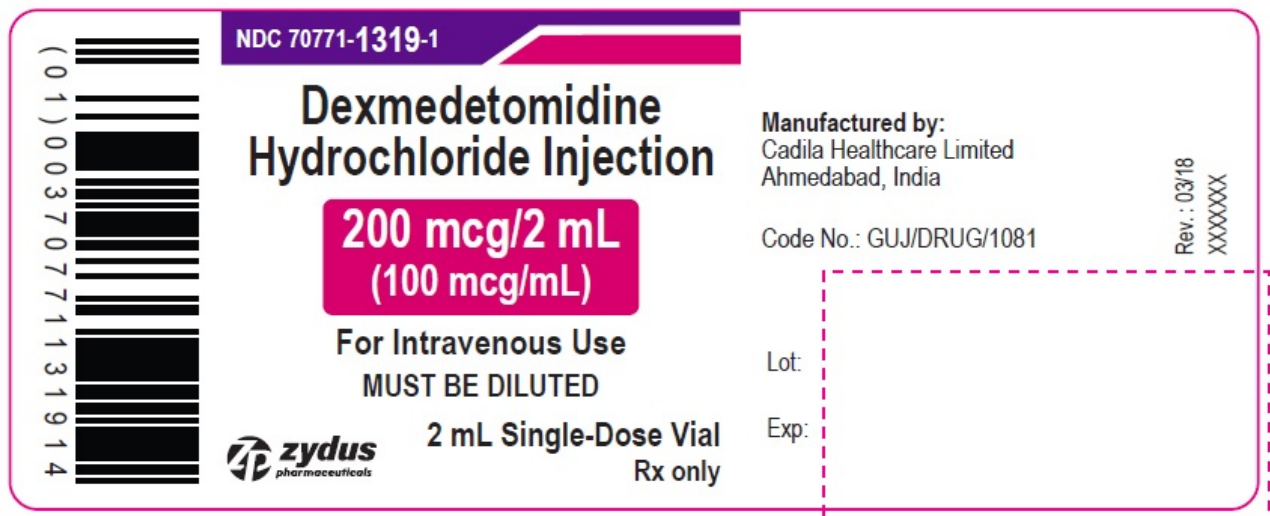
For Intravenous Infusion Use

MUST BE DILUTED

2 mL Single-Dose Vial

Rx only

Zydus Pharmaceuticals



**PRINCIPAL DISPLAY PANEL - 200 MCG/2 ML CARTON LABEL**

NDC 70771-1319-7

Dexmedetomidine

Hydrochloride Injection

200 mcg/2 mL

(100 mcg/mL)

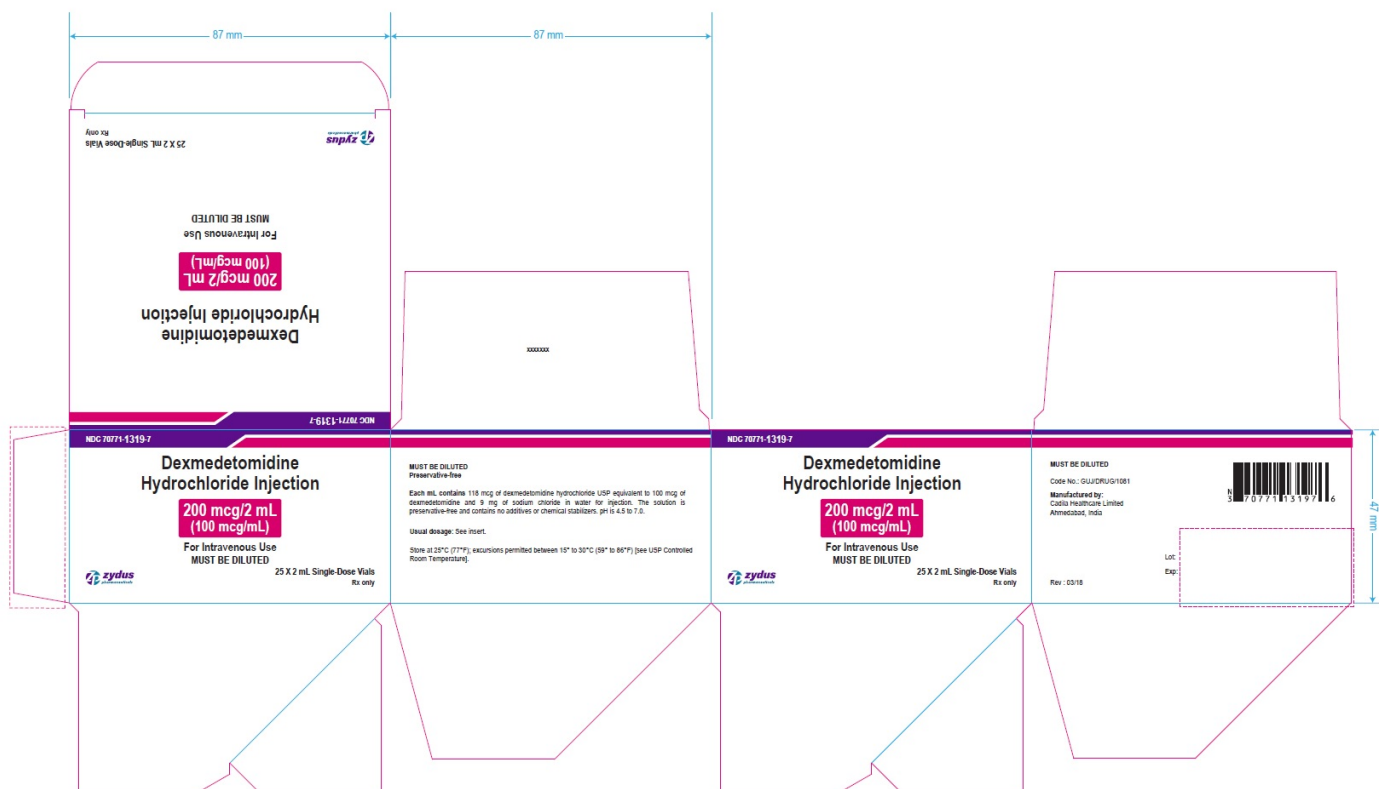
For Intravenous Infusion Use

MUST BE DILUTED

25 X 2 mL Single-Dose Vials

Rx only

Zydus Pharmaceuticals



## DEXMEDETOMIDINE HYDROCHLORIDE

dexmedetomidine hydrochloride injection, solution, concentrate

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1319
<b>Route of Administration</b>	INTRAVENOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXMEDETOMIDINE HYDROCHLORIDE (UNII: 1018WH7F9I) (DEXMEDETOMIDINE -	DEXMEDETOMIDINE	100 ug

UNII:67VB76HONO)		DEAMEDETOMIDINE	in 1 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
SODIUM CHLORIDE (UNII: 451W47IQ8X)			9 mg in 1 mL	
WATER (UNII: 059QF0KO0R)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1319-7	25 in 1 CARTON	06/14/2018	
1	NDC:70771-1319-1	2 mL in 1 VIAL; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA206798	06/14/2018		

**Labeler** - Zydus Lifesciences Limited (918596198)

**Registrant** - Zydus Lifesciences Limited (918596198)

### Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1319) , MANUFACTURE(70771-1319)

Revised: 10/2022

Zydus Lifesciences Limited