

DEXMEDETOMIDINE HYDROCHLORIDE- dexmedetomidine hydrochloride injection, solution, concentrate

Cadila Healthcare Limited

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

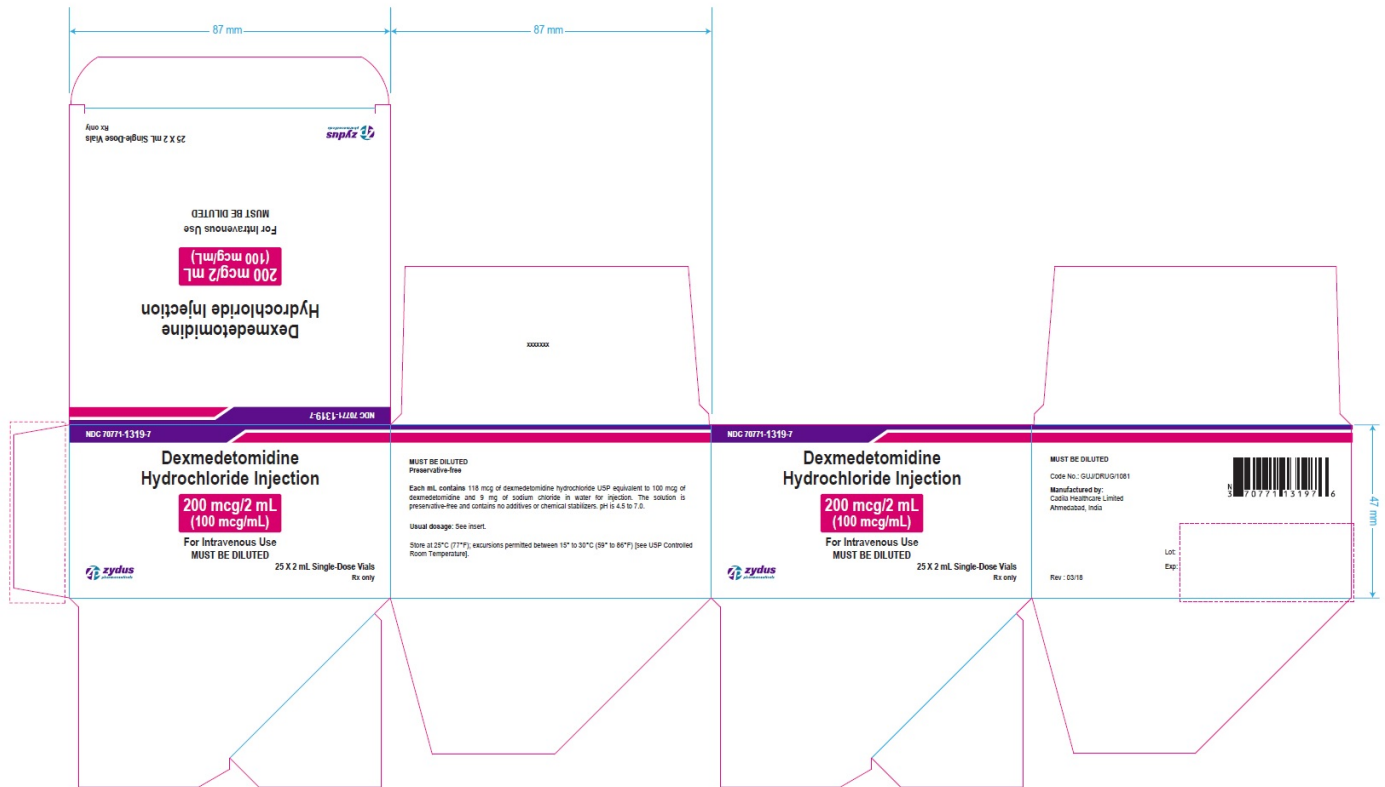
Dexmedetomidine

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

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXMEDETOMIDINE HYDROCHLORIDE (UNII: 10 18 WH7F9 I) (DEXMEDETOMIDINE - UNII:6 7 VB76 HONO)	DEXMEDETOMIDINE	100 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8 X)	9 mg in 1 mL
WATER (UNII: 0 59 QF0 KO0 R)	

Packaging

#	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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206798	06/14/2018	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

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

Revised: 10/2020

Cadila Healthcare Limited