

**CISATRACURIUM BESYLATE- cisatracurium besylate injection**  
**Cadila Healthcare Limited**

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**Cisatracurium Besalaye Injection, USP**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Container Label (20 mg/10 mL)

NDC 72758-0011-1

Cisatracurium Besylate Injection, USP

20 mg/10 mL\*

(2 mg/mL)

WARNING: Paralyzing Agent

For Intravenous Injection

0.9% benzyl alcohol (added as a preservative)

10 mL Multiple-Dose Vial

Rx only

(01)00372758001111

Store at 2° to 8°C (36° to 46°F) in the carton. Do not freeze. Protect from light. Upon removal from refrigeration, use within 21 days even if rerefrigerated.

Discard by: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Code No.: GUJ/DRUGS/G/28/1609  
Made in India  
Rev : 09/20

NDC 72758-0011-1

**Cisatracurium Besylate Injection, USP**

**20 mg/10 mL\***  
**(2 mg/mL)**

**WARNING: Paralyzing Agent**  
For Intravenous Injection  
0.9% benzyl alcohol (added as a preservative)

**WARNING: Paralyzing Agent.**  
**Causes Respiratory Arrest.**  
**Facilities must be immediately available for artificial respiration.**  
A sterile, nonpyrogenic solution for intravenous injection.  
\*Each mL contains cisatracurium 2 mg equivalent to cisatracurium besylate, USP 2.68 mg, with 0.9% w/v benzyl alcohol.  
Usual Dosage: See package insert.

Lot: \_\_\_\_\_  
Exp: \_\_\_\_\_

**zydus** pharmaceuticals  
10 mL Multiple-Dose Vial  
Rx only

Carton Label (20 mg/10 mL)

NDC 72758-0011-1

Cisatracurium Besylate Injection, USP

20 mg/10 mL\*

(2 mg/mL)

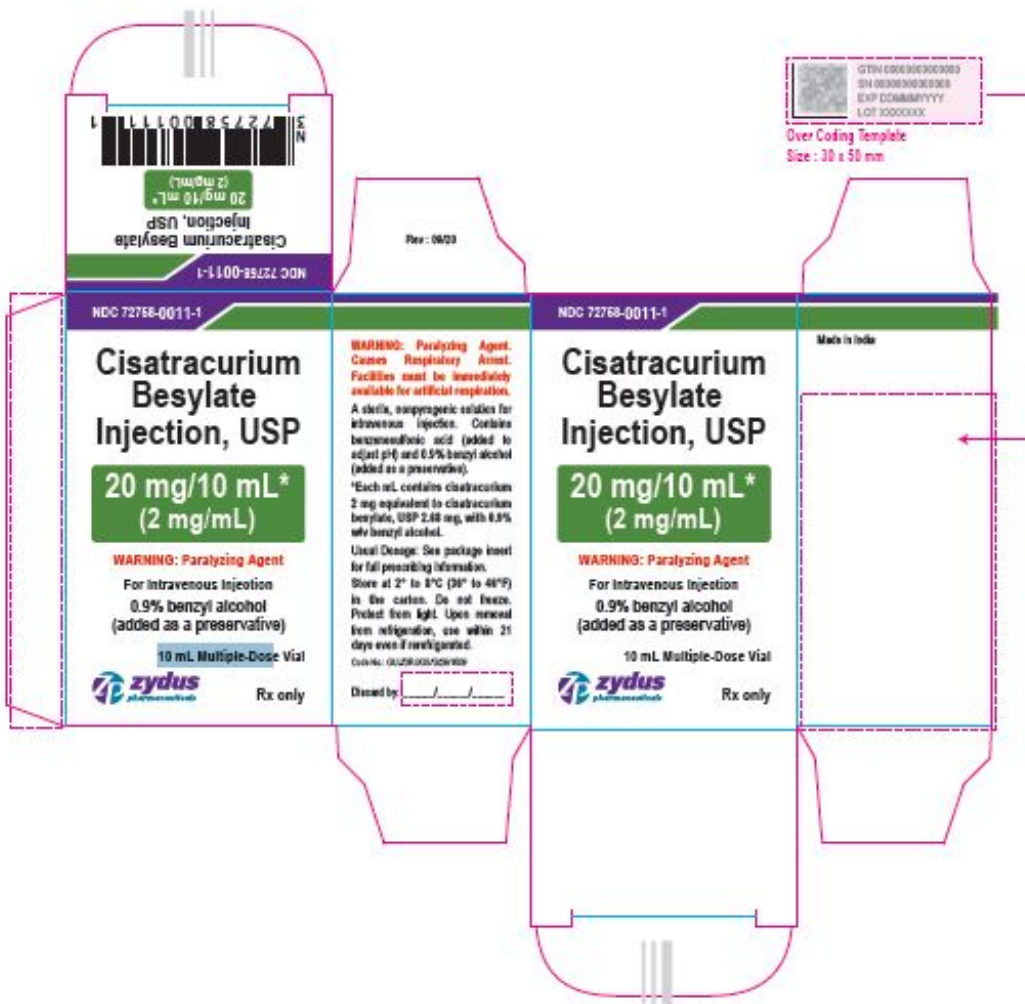
WARNING: Paralyzing Agent

For Intravenous Injection

0.9% benzyl alcohol (added as a preservative)

10 mL Multiple-Dose Vial

Rx only



Carton Label (20 mg/10 mL)

NDC 72758-0011-6

Cisatracurium Besylate Injection, USP

20 mg/10 mL\*

(2 mg/mL)

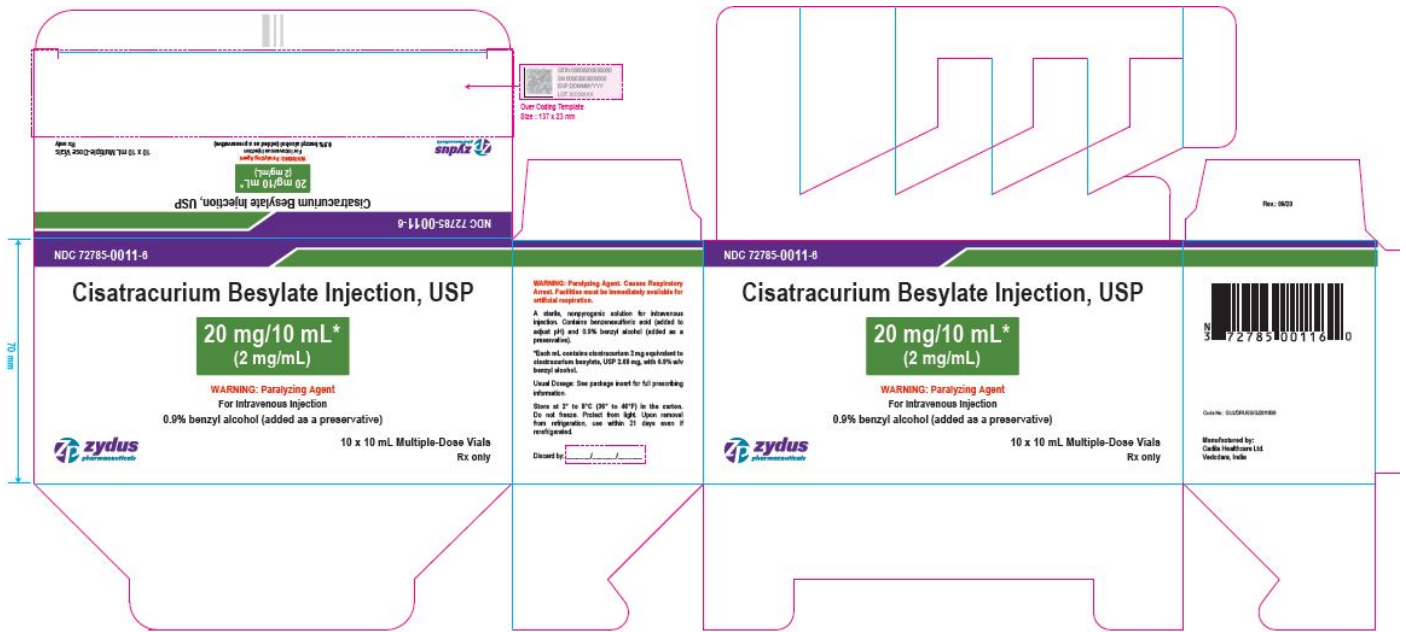
WARNING: Paralyzing Agent

For Intravenous Injection

0.9% benzyl alcohol (added as a preservative)

10 x 10 mL Multiple-Dose Vial

Rx only



## CISATRACURIUM BESYLATE

cisatracurium besylate injection

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72785-0011
Route of Administration	INTRAVENOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CISATRACURIUM BESYLATE (UNII: 80 YS8O1MBS) (CISATRACURIUM - UNII:QX62KLI41N)	CISATRACURIUM	2 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
BENZENESULFONIC ACID (UNII: 685928Z18A)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72785-0011-6	10 in 1 CARTON	11/05/2020	
1	NDC:72785-0011-1	10 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	ANDA213527	11/05/2020	

**Labeler** - Cadila Healthcare Limited (873671928)

**Registrant** - Cadila Healthcare Limited (873671928)

**Establishment**

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		873671928	MANUFACTURE(72785-0011) , ANALYSIS(72785-0011)

Revised: 9/2020

Cadila Healthcare Limited