

CISATRACURIUM BESYLATE- cisatracurium besylate injection
Cadila Healthcare Limited

CISATRACURIUM BESYLATE INJECTION

Principal Display Panel – Container Label (10 mg/5 mL)

NDC 72785-0008-1

Cisatracurium Besylate Injection, USP

10 mg/5 mL*

(2 mg/mL)

WARNING: Paralyzing Agent

For Intravenous Injection

Preservative free

5 mL Single-Dose Vial

Rx only

Zydus Pharmaceuticals

The image shows a detailed container label for Cisatracurium Besylate Injection, USP. The label is rectangular with a purple and orange header. On the left side, there is a vertical barcode with the number (01)00372785000811 printed vertically. The main text on the label includes: 'NDC 72785-0008-1' in a purple box; 'Cisatracurium Besylate Injection, USP' in large black font; '10 mg/5 mL* (2 mg/mL)' in an orange box; 'For Intravenous Injection Preservative free'; '5 mL Single-Dose Vial Rx only'; and the Zydus Pharmaceuticals logo. On the right side, there is a red warning: 'Warning: Paralyzing Agent. Causes Respiratory Arrest. Facilities must be immediately available for artificial respiration.' followed by a description of the solution and its use. At the bottom right, there are fields for 'Lot:' and 'Exp:' with a dashed border around them. The label also includes storage instructions, a discard date field, and 'Made in India' and 'Rev: 12/19'.

Refrigerate: Store at 2° to 8°C (36° to 46°F) in the carton. Do not freeze. Protect from light.

Upon removal from refrigeration to room temperature, use within 21 days even if rerefrigerated.

Discard by: ____/____/____

Made in India

Rev: 12/19

NDC 72785-0008-1

Cisatracurium Besylate Injection, USP

10 mg/5 mL* (2 mg/mL)

For Intravenous Injection
Preservative free

zydus pharmaceuticals

5 mL Single-Dose Vial
Rx only

Warning: Paralyzing Agent. Causes Respiratory Arrest. Facilities must be immediately available for artificial respiration.

A sterile, nonpyrogenic solution for intravenous injection. Contains benzenesulfonic acid (added to adjust pH).

*Each mL contains cisatracurium besylate, USP equivalent to 2 mg cisatracurium.

Usual Dosage: See package insert.

Lot: _____

Exp: _____

Principal Display Panel – Container Label (200 mg/20 mL)

NDC 72785-0009-1

Cisatracurium Besylate Injection, USP

200 mg/20 mL*

(10 mg/mL)

WARNING: Paralyzing Agent

For ICU use only.

For Intravenous Injection

Preservative free

20 mL Single-Dose Vial

Rx only

Zydus Pharmaceuticals

NDC 72785-0009-1

Cisatracurium Besylate Injection, USP

200 mg/20 mL* (10 mg/mL)

For ICU use only.

For Intravenous Injection
Preservative free

zydus pharmaceuticals

20 mL Single-Dose Vial
Rx only

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

Discard by: ____/____/____

Made in India

Rev: 12/19

Warning: Paralyzing Agent. Causes Respiratory Arrest. Facilities must be immediately available for artificial respiration.

A sterile, nonpyrogenic solution for intravenous injection. Contains benzenesulfonic acid (added to adjust pH). *Each mL contains cisatracurium besylate, USP equivalent to 10 mg cisatracurium.

Usual Dosage: See package insert.

Lot: _____

Exp: _____

Principal Display Panel – Carton Label (10 mg/5 mL)

NDC 72785-0008-6

Cisatracurium Besylate Injection, USP

10 mg/5 mL*

(2 mg/mL)

WARNING: Paralyzing Agent

For Intravenous Injection

Preservative free

10 x 5 mL Single-Dose Vials

Rx only

Zydus Pharmaceuticals

NDC 72785-0008-6

Cisatracurium Besylate Injection, USP

10 mg/5 mL* (2 mg/mL)

For Intravenous Injection
Preservative free

10 x 5 mL Single-Dose Vials
Rx only

zydus pharmaceuticals

Warning: Paralyzing Agent. Causes Respiratory Arrest. Facilities must be immediately available for artificial respiration.

A sterile, nonpyrogenic solution for intravenous injection. Contains benzenesulfonic acid (added to adjust pH). *Each mL contains cisatracurium besylate, USP equivalent to 2 mg cisatracurium.

Usual Dosage: See package insert for full prescribing information.

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

Discard by: ____/____/____

Rev: 12/19

NDC 72785-0008-6

Cisatracurium Besylate Injection, USP

10 mg/5 mL* (2 mg/mL)

For Intravenous Injection
Preservative free

10 x 5 mL Single-Dose Vials
Rx only

zydus pharmaceuticals

Manufactured by:
Lila Pharmaceuticals Ltd.
Vadodra, India

Principal Display Panel – Carton Label (200 mg/20 mL)

NDC 72785-0009-6

Cisatracurium Besylate Injection, USP

200 mg/20 mL*

(10 mg/mL)

WARNING: Paralyzing Agent

For ICU use only.

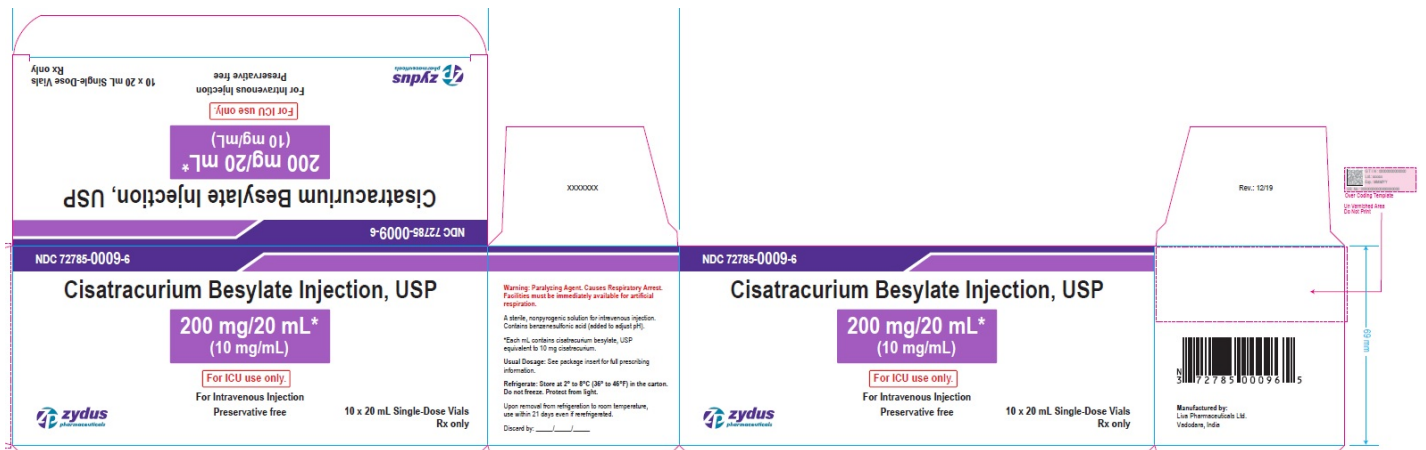
For Intravenous Injection

Preservative free

10 x 20 mL Single-Dose Vials

Rx only

Zydus Pharmaceuticals



CISATRACURIUM BESYLATE

cisatracurium besylate injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72785-0008
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CISATRACURIUM BESYLATE (UNII: 80 YS8O 1MBS) (CISATRACURIUM - UNII:QX62KLI41N)	CISATRACURIUM	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZENESULFONIC ACID (UNII: 685928 Z18 A)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72785-0008-6	10 in 1 CARTON	02/12/2020	
1	NDC:72785-0008-1	5 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	ANDA212171	02/12/2020	

CISATRACURIUM BESYLATE

cisatracurium besylate injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72785-0009
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CISATRACURIUM BESYLATE (UNII: 80YS8O1MBS) (CISATRACURIUM - UNII:QX62KLI41N)	CISATRACURIUM	10 mg in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72785-0009-6	10 in 1 CARTON	02/12/2020	
1	NDC:72785-0009-1	20 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	ANDA212171	02/12/2020	

Labeler - Cadila Healthcare Limited (873671928)