

CISATRACURIUM BESYLATE - cisatracurium besylate injection
Zydus Lifesciences 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 white background and purple and orange accents. On the left side, there is a vertical barcode with the number (01)00372785000811 printed vertically. The top left corner contains storage instructions: 'Refrigerate: Store at 2° to 8°C (36° to 46°F) in the carton. Do not freeze. Protect from light.' Below this, it says 'Upon removal from refrigeration to room temperature, use within 21 days even if rerefrigerated.' A 'Discard by:' field is present with a blank line for the date. Below that, it says 'Made in India' and 'Rev: 12/19'. The top center features the NDC number 'NDC 72785-0008-1' in a purple box. The main product name 'Cisatracurium Besylate Injection, USP' is prominently displayed in black. Below the name, the concentration '10 mg/5 mL* (2 mg/mL)' is shown in an orange box. Further down, it states 'For Intravenous Injection' and 'Preservative free'. The Zydus Pharmaceuticals logo is at the bottom left. The bottom right corner includes '5 mL Single-Dose Vial' and 'Rx only'. On the right side, there is a red warning: 'Warning: Paralyzing Agent. Causes Respiratory Arrest. Facilities must be immediately available for artificial respiration.' Below the warning, it describes the product as a sterile, nonpyrogenic solution for intravenous injection, containing benzenesulfonic acid. It also states '*Each mL contains cisatracurium besylate, USP equivalent to 2 mg cisatracurium.' and 'Usual Dosage: See package insert.' At the bottom right, there are fields for 'Lot:' and 'Exp:' with a dashed red box around them.

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

(01)00372785000910

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 72785-0009-1

Cisatracurium Besylate Injection, USP

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

For ICU use only.

For Intravenous Injection
Preservative free
20 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 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

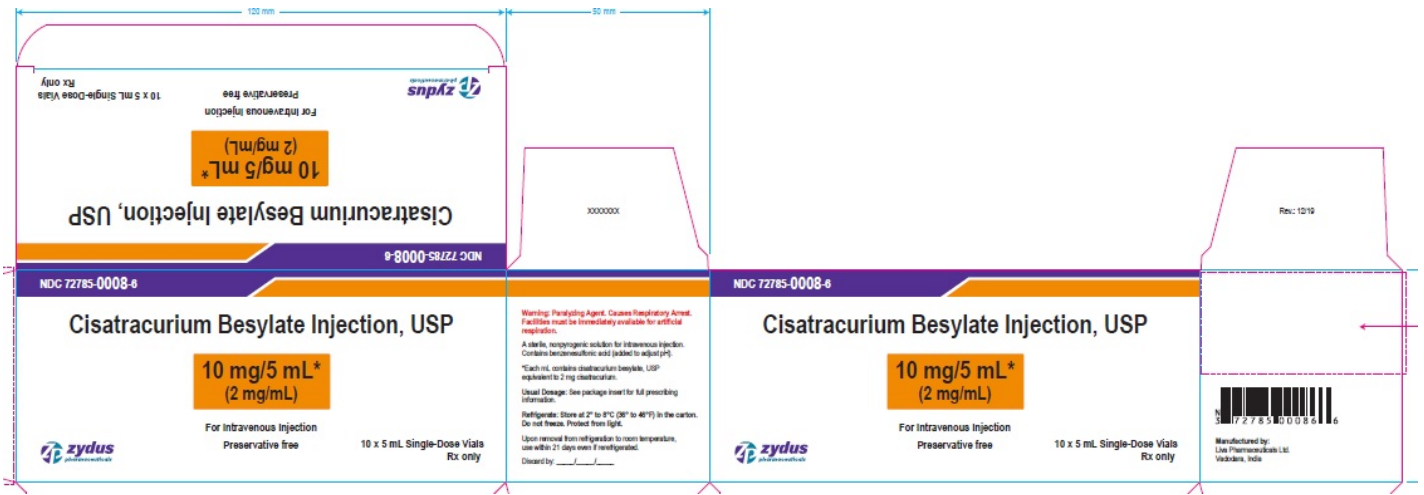
For Intravenous Injection

Preservative free

10 x 5 mL Single-Dose Vials

Rx only

Zydus Pharmaceuticals



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.

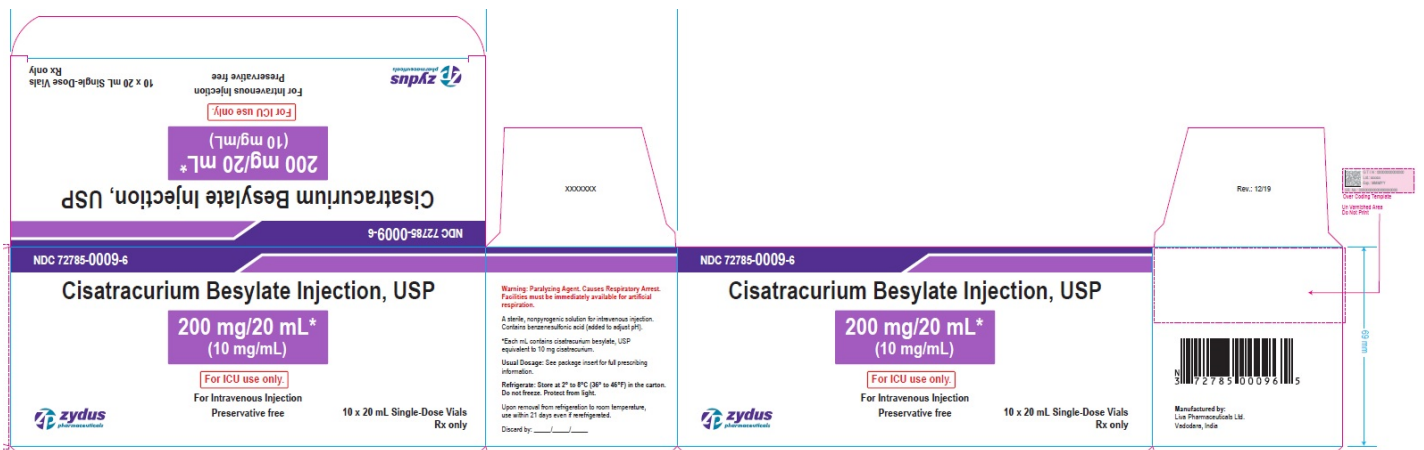
For Intravenous Injection

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: 80YS8O1MBS) (CISATRACURIUM - UNII:QX62KLI41N)	CISATRACURIUM	2 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:72785-0008-6	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 - Zydus Lifesciences Limited (873671928)

Revised: 11/2022

Zydus Lifesciences Limited