

**DEVICE - NEBUCLEAR MD HAND-HELD RUBBER BULB NEBULIZER- device -
hand-held rubber bulb nebulizer aerosol, spray
Blue Echo Care LLC**

Description

This device is a non-sterile hand-held rubber bulb nebulizer intended to aerosolize bronchodilators for inhalation.

This product is listed and approved for over-the-counter use under Monograph M012.

This product contains no active or inactive ingredients.

Uses

Please consult the use section of the OTC bronchodilator drug label approved for use with this device.

Warnings

Please consult the warnings section for the OTC bronchodilator drug label before use with this device.

Please consult the purpose section of the OTC bronchodilator drug label approved for use with this device.

This is the device only and includes no active or inactive ingredients.

Keep out of reach of small children

Directions

- Connect bulb to solutions cup.
- Open top of cup, add approved Bronchodilator, close solutions cup.
- Squeeze bulb vigorously so visible vapor comes from the top.
- Breathe in slowly until approved Bronchodilator is gone.
- Disconnect bulb and follow Cleaning Instructions.

Cleaning Instructions

- Soak solutions cup in warm, soapy water for 10 minutes.
- Rinse in warm water.
- Let air dry.



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Product Information

Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:73117-521	
Route of Administration		RESPIRATORY (INHALATION)			
Active Ingredient/Active Moiety					
Ingredient Name			Basis of Strength	Strength	
RACEPINEPHRINE HYDROCHLORIDE (UNII: 336096P2WE) (EPINEPHRINE,(+/-)- - UNII:GR0L9S3J0F)			EPINEPHRINE,(+/-)-	11.25 mg in 0.5 mL	
Inactive Ingredients					
Ingredient Name			Strength		
WATER (UNII: 059QF0KO0R)					
Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:73117-521-23	1 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/18/2025		
Marketing Information					
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug		M012	11/18/2025		

Labeler -
Blue Echo Care LLC (117048847)

Establishment			
Name	Address	ID/FEI	Business Operations
Blue Echo Care LLC		117048847	manufacture(73117-521)