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

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## **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 secton 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.

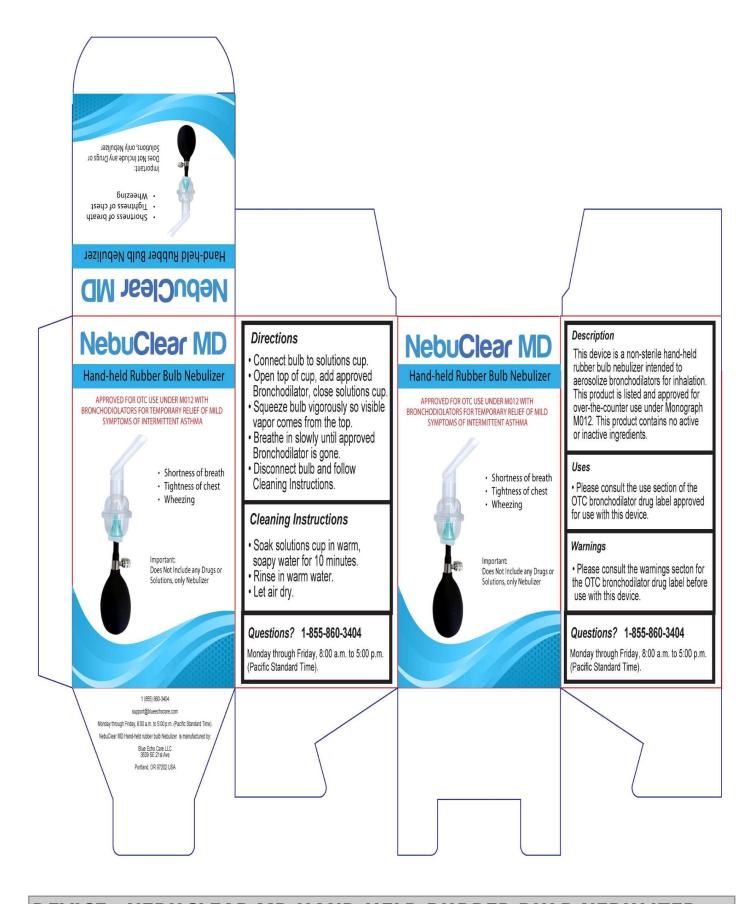
Keep out of reach of small children

#### **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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device - hand-held rubber bulb nebulizer aerosol, spray

#### **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 RACEPINEPHRINE HYDROCHLORIDE (UNII: 336096P2WE) (EPINEPHRINE,(+/-)- UNII:GROL9S3J0F) EPINEPHRINE,(+/-)- 11.25 mg in 0.5 mL

Inactive Ingredients			
	Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)			

ı	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)		

Revised: 11/2025 Blue Echo Care LLC