

SINU INHALER- levmetamfetamine nasal decongestant inhalant

NeilMed

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient (per inhaler)

Levmetamfetamine 50 mg

Purpose

Nasal decongestant

Use for temporary relief of nasal congestion due to:

- the common cold
- hay fever or upper respiratory allergies

Warnings

When using this product

- **do not exceed recommended dosage**
- temporary burning, stinging, sneezing, or increased nasal discharge may occur
- use of this container by more than one person may spread infection
- do not use for more than 7 days
- Use only as directed
- frequent or prolonged use may cause nasal congestion to recur or worsen

Stop use and ask a doctor if

symptoms persist

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- the product delivers in each 800 ml of air 0.04 to 0.150 mg of levmetamfetamine
- do not use more often than every 2 hours

adults and children 12 years of age and over
children 6 to under 12 years of age

2 inhalations in each nostril
1 inhalation in each nostril

(with adult supervision)
children under 6 years of age
children under 2 years of age

1 inhalation in each nostril

ask a doctor
do not use

Other Information

- this inhaler is effective for a minimum of 3 months after first use
- keep inhaler tightly closed
- store at 59°-86°F (15°- 30°C)

Inactive Ingredients:

bornyl acetate, camphor, lavender oil, menthol, methyl salicylate

Questions or comments? 1-707-525-3784

TAMPER EVIDENT - USE ONLY IF PERFORATED TUBE LABEL IS INTACT

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www.NeilMed.com Made in the USA BCNM01 Rev. 04/14

PRINCIPAL DISPLAY PANEL - Sinu Inhaler

NEW

NDC 13709-281-07

NeilMed®

Sinu Inhaler™

Nasal Decongestant

Levmetamfetamine - Nasal Decongestant

Temporary

Relief of Nasal Congestion due to:

Upper Respiratory Allergies

Cold • Hay Fever

Net Wt 0.007 OZ (198 mg) See Drug Facts

6031-ENU-US-rev1-PP20140409zm



SINU INHALER

levmetamfetamine nasal decongestant inhalant

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13709-281
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVMETAMFETAMINE (UNII: Y24T9BT2Q2) (LEVMETAMFETAMINE - UNII:Y24T9BT2Q2)	LEVMETAMFETAMINE	50 mg

Inactive Ingredients

Ingredient Name	Strength
BORNYL ACETATE (UNII: 213431586X)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13709-281-07	1 in 1 BLISTER PACK	06/15/2014	

1	198 in 1 INHALER; Type 0: Not a Combination Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/15/2014	

Labeler - NeilMed (783557783)

Registrant - Aphenia Pharma Solutions-New York, LLC (078573647)

Establishment

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions-Maryland, LLC		829739833	manufacture(13709-281) , pack(13709-281) , label(13709-281)

Revised: 12/2018

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