

**SINU INHALER- levmetamfetamine nasal decongestant inhalant**  
**NeilMed Pharmaceuticals, Inc.**

*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	2 inhalations in each nostril
children 6 to under 12 years of age (with adult supervision)	1 inhalation in each nostril
children under 6 years of age	ask a doctor
children under 2 years of age	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**

**DISTRIBUTED BY NeilMed® Pharmaceuticals, Inc.**

**601 Aviation Blvd., Santa Rosa, CA 95403 USA**

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



**TAMPER EVIDENT – USE ONLY IF PERFORATED TUBE LABEL IS INTACT.**

<b>Drug Facts</b>	
<b>Active ingredient (per inhaler)</b>	<b>Purpose</b>
Levmetamfetamine 50 mg	Nasal decongestant
<b>Use</b> for temporary relief of nasal congestion due to:	
• the common cold	• hay fever or upper respiratory allergies
<b>Warnings:</b>	
<b>When using this product:</b>	
• 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	
<b>Stop use and ask a doctor if symptoms persist</b>	
<b>If pregnant or breast-feeding</b> , ask a health professional before use	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
• 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	2 inhalations in each nostril
children 6 to under 12 years of age (with adult supervision)	1 inhalation in each nostril
children under 6 years of age	ask a doctor
children under 2 years of age	do not use
<b>Other information</b> • 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)	
<b>Inactive ingredients</b> bormyl acetate, camphor, lavender oil, menthol, methyl salicylate	
<b>Questions or comments?</b> 1-707-525-3784	
<small>Distributed By: NeilMed® Pharmaceuticals, Inc.          601 Aviation Blvd, Santa Rosa, CA 95403 USA          www.neilmed.com Made in the USA BCNM01A Rev. 04/20</small>	

## SINU INHALER

levmetamfetamine nasal decongestant inhalant

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13709-281
<b>Route of Administration</b>	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)	

<b>Camphor (Synthetic)</b> (UNII: 5TJD82A1ET)	
<b>Lavender oil</b> (UNII: ZBP1YXW0H8)	
<b>Menthol</b> (UNII: L7T10EIP3A)	
<b>Methyl Salicylate</b> (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 Pharmaceuticals, Inc. (799295915)

**Registrant** - Aphenia Pharma Solutions MD, LLC (829739833)

### Establishment

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions MD, LLC		829739833	MANUFACTURE(13709-281)

Revised: 12/2018

NeilMed Pharmaceuticals, Inc.