

# VAPOR INHALER LEVMETAMFETAMINE NASAL DECONGESTANT, GOOD SENSE

- levmetamfetamine inhalant

Geiss, Destin & Dunn, 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?**

**1-866-696-0957**

### **Principal Display Panel - 198 mg Blister Pack Label**

**GOODSENSE®**

NDC 50804-281-07

***Nasal Decongestant***

***Vapor Inhaler***

***Levmetamfetamine • Nasal Decongestant***

***Temporary Relief of  
Nasal Congestion due to:***

- ***Colds • Hay Fever***
- ***Upper Respiratory Allergies***

**NET WT**

**.007 oz (198 mg)**

***\*Compare to active ingredient of  
Vicks® VapoInhaler®***

**100%**

**SATISFACTION**

**GUARANTEED**



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

\*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® VapoInhaler®, Vicks® VapoInhaler® is a trademark of Procter & Gamble

| <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>  |                               |
| • <b>do not exceed recommended dosage</b>   |                               |
| • 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, ask a health professional before use.</b>   |                               |
| <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> borneyl acetate, camphor, lavender oil, menthol, methyl salicylate  |                               |
| <b>Questions or comments?</b> 1-866-696-0957  |                               |
| <small>Distributed By: Geiss, Destin &amp; Dunn, Inc., Peachtree City, GA 30269<br/>www.valuelabels.com<br/>Made in the USA      BCGS01      Rev. 06/13</small>         |                               |

## VAPOR INHALER LEVMEFAMFETAMINE NASAL DECONGESTANT, GOOD SENSE

levmetamfetamine inhalant

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:50804-281 |
| <b>Route of Administration</b> | NASAL          |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength |
|---|-------------------|----------|
| <b>Levmetamfetamine</b> (UNII: Y24T9BT2Q2) (Levmetamfetamine - UNII:Y24T9BT2Q2) | Levmetamfetamine  | 50 mg    |

### Inactive Ingredients

| Ingredient Name                               | Strength |
|---|----------|
| <b>Borneyl acetate</b> (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:50804-281-07 | 1 in 1 BLISTER PACK  | 03/08/2021           |                    |
| 1 |                  | 198 in 1 INHALER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.) |                      |                    |

## Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341                                  | 03/08/2021           |                    |

**Labeler** - Geiss, Destin & Dunn, Inc. (076059836)

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

## Establishment

| Name                             | Address | ID/FEI    | Business Operations    |
|----------------------------------|---------|-----------|------------------------|
| Aphenia Pharma Solutions MD, LLC |         | 829739833 | MANUFACTURE(50804-281) |

Revised: 2/2023

Geiss, Destin & Dunn, Inc.