

**VAPOR INHALER LEVMETAMFETAMINE NASAL DECONGESTANT, TOPCARE HEALTH - levmetamfetamine inhalant
Topco Associates LLC**

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 50mg

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

Principal Display Panel - 198 mg Blister Pack Label

NDC 36800-294-07

+**TopCare**® health™

**Vapor
Inhaler**

**OUR PHARMACISTS
RECOMMENDED**

LEVAMETAMFETAMINE - NASAL DECONGESTANT

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

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

NET WT 0.007 OZ (198mg)

NDC 36800-294-07

+TopCare® health™

Vapor Inhaler



LEVMETAMFETAMINE - NASAL DECONGESTANT

Temporary Relief of Nasal Congestion Due to:
• Colds • Hay Fever
• Upper Respiratory Allergies

NET WT 0.007 OZ (198mg)

TAMPER EVIDENT — USE ONLY IF PERFORATED TUBE LABEL IS INTACT.

BCTP01C
Rev. 09/17

Drug Facts

Purpose

Active ingredient per inhaler:

Levmetamfetamine 50mg Nasal Decongestant

Use: For temporary relief of nasal congestion due to
■ the common cold ■ hay fever or upper respiratory allergies

Warnings

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Inactive ingredients borneyl acetate, camphor, lavender oil, menthol, methyl salicylate

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topcare@topco.com www.topcarebrand.com

✓ QUALITY GUARANTEED

This Top Care® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.



Principal Display Panel - 198 mg Inhaler Label

NDC 36800-294-07

+TopCare®
health™

**Vapor
Inhaler**

LEVMETAMFETAMINE - NASAL DECONGESTANT

NET WT 0.007 OZ (198mg)

NON VARNISH AREA

NDC 36800-294-07



Vapor Inhaler

NET WT 0.007 OZ (198mg)

LEVMETAMFETAMINE - NASAL DECONGESTANT

TAMPER EVIDENT-USE ONLY IF PERFORATED TUBE LABEL IS INTACT.

PEEL HERE THEN TWIST TO OPEN

Active ingredient (per inhaler) **Purpose**
Levmetamfetamine 50 mg.....Nasal decongestant

Use for temporary relief of nasal congestion due to:
 ■ the common cold
 ■ hay fever or other upper respiratory allergies

Warnings

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LATP01D
Rev. 09/17

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✓ QUALITY GUARANTEED

VAPOR INHALER LEVMETAMFETAMINE NASAL DECONGESTANT, TOPCARE HEALTH

levmetamfetamine inhalant

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-294
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 (UNII: L7T10EIP3A)	
Methyl Salicylate (UNII: LAV5U5022Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-294-07	1 in 1 BLISTER PACK	02/19/2021	
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	02/19/2021	

Labeler - Topco Associates LLC (006935977)**Registrant** - Aphenia Pharma Solutions MD, LLC (829739833)**Establishment**

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions MD, LLC		829739833	MANUFACTURE(36800-294)

Revised: 2/2023

Topco Associates LLC