

**VAPOR INHALER- levmetamfetamine nasal decongestant inhalant
C.D.M.A., 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
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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?

800-935-2362

Principal Display Panel - 198 mg Blister Pack Label

NDC 63868-267-01

QC®

**QUALITY
CHOICE**

Vapor Inhaler

Nasal Decongestant

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


Colds,

Hay Fever

Upper Respiratory Allergies

NET WT 0.007 OZ (198 mg)


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

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Distributed by C.D.M.A., Inc.®
 43157 W. Nine Mile
 Novi, MI 48376-0995
 www.qualitychoice.com
 Questions: 800-935-2362



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Made in the USA BCQC01A Rev. 08/21

VAPOR INHALER

levmetamfetamine nasal decongestant inhalant

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-267
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
Borneyl 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:63868-267-01	1 in 1 BLISTER PACK	01/01/2014	
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	01/01/2014	

Labeler - C.D.M.A., Inc. (011920774)

Registrant - Aphenia Pharma Solutions MD, LLC (829739833)

Establishment

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions MD, LLC		829739833	MANUFACTURE(63868-267)

Revised: 2/2023

C.D.M.A., Inc.