LEVMETAMFETAMINE- levmetamfetamine inhalant Meijer, 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	1 inhalation in each nostril

supervision)	
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? 1-877-586-7979

Principal Display Panel - 198 mg Label

meijer®

NDC 79481-0300-1

Vapor Inhaler

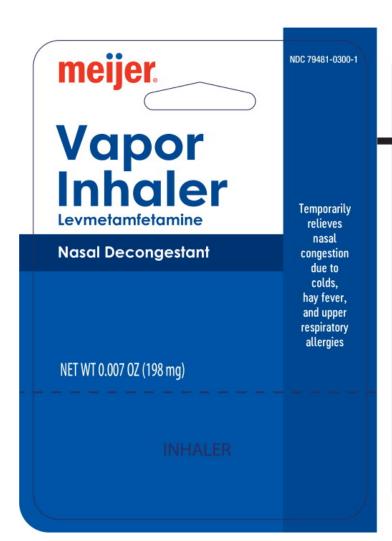
Levmetamfetamine

Nasal Decongestant

Temporarily relieves nasal congestion due to colds, hay fever, and upper respiratory allergies

NET WT 0.007 OZ (198 mg)

INHALER



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





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DIST. BY MEIJER DISTRIBUTION, INC., GRAND RAPIDS, MI 49544 www.meijer.com Made in the USA

P/N BCMJ01C Rev. 05/23



LEVMETAMFETAMINE

levmetamfetamine inhalant

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:79481-0300

Route of Administration NASAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength Strength

Strength

Levmetamfetamine (UNII: Y24T9BT2Q2) (Levmetamfetamine - UNII:Y24T9BT2Q2) | Levmetamfetamine | 50 mg

Inactive Ingredients Ingredient Name 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:79481- 0300-1	1 in 1 BLISTER PACK	09/29/2023	
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	09/29/2023	

Labeler - Meijer, Inc. (006959555)

Registrant - Aphena Pharma Solutions - Maryland, LLC (829739833)

Establishment			
Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions - Maryland, LLC		829739833	MANUFACTURE(79481-0300)

Revised: 7/2023 Meijer, Inc.