

# VAPOR INHALER - levmetamfetamine nasal decongestant inhalant

## Walgreens

*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	1 inhalation in each nostril

(with adult 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?**

**1-800-walgreens (1-800-925-4733)**

**Principal Display Panel - 3 Inhaler Carton****VALUE SIZE**

NDC 0363-0564-53

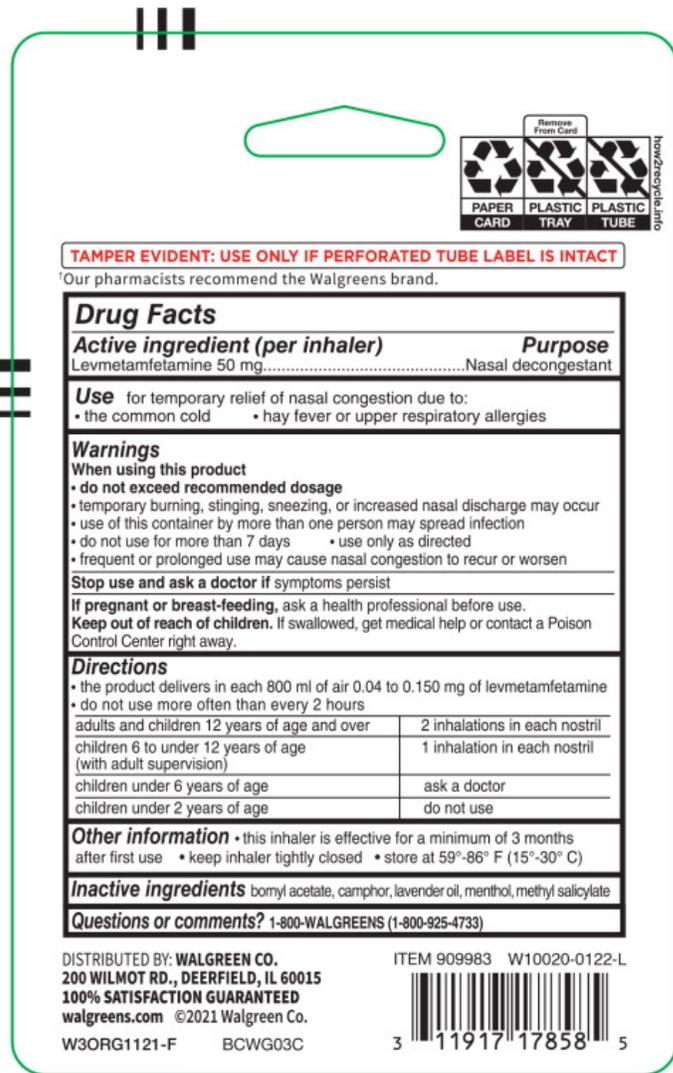
Contains 3 of NDC 0363-0564-50

***Walgreens*****WALGREENS PHARMACIST RECOMMENDED****Vapor Inhaler****LEVAMETAMFETAMINE / NASAL DECONGESTANT****Nasal Decongestant**

NET WT 0.007 OZ (198 mg) PER INHALER

TOTAL NET WT 0.021 OZ (594 mg)

**3  
INHALERS**



## VAPOR INHALER

levmetamfetamine nasal decongestant inhalant

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-0564
<b>Route of Administration</b>	NASAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>BORNYL 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:0363-0564-50	1 in 1 BLISTER PACK	07/01/2016	
1		198 in 1 INHALER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:0363-0564-53	3 in 1 BLISTER PACK	07/01/2016	
2		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	07/01/2016	

**Labeler** - Walgreens (008965063)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions-Maryland, LLC		829739833	manufacture(0363-0564) , pack(0363-0564) , label(0363-0564)

Revised: 3/2023

Walgreens