

**VAPOR INHALER- levmetamfetamine nasal decongestant inhalant
Cardinal Health (Leader)**

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
children 6 to under 12 years of age

2 inhalations in each nostril
1 inhalation in each nostril

(with adult supervision)
children under 6 years of age
children under 2 years of age

1 inhalation in each nostril

ask a doctor

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

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.

All **Leader®** Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund

DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313 CIN 4914057

Made in the USA BCLE01 Rev. 06/13

PRINCIPAL DISPLAY PANEL - Vapor Inhaler

Leader

NDC 49781-045-98

Compare to Vicks® VapoInhaler®

active ingredient*

Nasal Decongestant

Vapor Inhaler

Levmetamfetamine • Nasal Decongestant

Temporary Relief of Nasal Congestion due to:

- Colds • Hay Fever
- Upper Respiratory Allergies

Satisfaction Guaranteed

NET WT .007 oz (198 mg)

NDC 49781-045-98

LEADER

*Compare to
Wicks® Vaporinhaler®
active ingredient*

**Nasal Decongestant
Vapor Inhaler**

Levmetamfetamine • Nasal Decongestant

Temporary Relief of Nasal Congestion due to:

- Colds • Hay Fever
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 **NET WT
.007 oz (198 mg)**


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This product and its manufacturer are not to be used by Patients & General Inhalation Use. Equivalence to Wicks® Vaporinhaler® active ingredient of Wicks & Gable.

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Questions or comments? 1-877-586-7973	

DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017
www.myleader.com 1-800-230-8313 CN 4914052
Made in the USA BCL91 Rev. 06/13



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VAPOR INHALER

levmetamfetamine nasal decongestant inhalant

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49781-045
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:49781-045-98	1 in 1 BLISTER PACK		
1		198 in 1 INHALER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/01/2014	

Labeler - Cardinal Health (Leader) (097537435)

Registrant - Aphena Pharma Solutions-New York, LLC (078573647)

Establishment

Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions-New York, LLC		078573647	manufacture(49781-045) , pack(49781-045) , label(49781-045)