

NASAL DECONGESTANT INHALER- levmetamfetamine nasal decongestant inhalant Aphena Pharma Solutions

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

Distributed & Manufactured by: Aphenia Pharma Solutions

7978 Industrial Park Road, Easton, MD 21601 USA

www.aphenapharma.com

Made in the USA BCAPS01 Rev. 01/17, LAAPS01 Rev. 01/17

PRINCIPAL DISPLAY PANEL - Vapor Inhaler

□

NDC 54884-050-01

Aphenia Pharma Solutions

Nasal Decongestant Inhaler

Levmetamfetamine

Levmetamfetamine 50mg - Nasal Decongestant

Use for temporary relief of nasal congestion
due to:

- the common cold
- hay fever or upper respiratory allergies

Net Wt 0.007 OZ (198 mg) Per Inhaler See Drug Facts

NON VARNISH AREA



NDC 54884-050-01

NASAL DECONGESTANT INHALER LEVMETAMFETAMINE

NET WT .007 oz (198 mg)

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

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

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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

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■ 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 boronyl acetate, camphor, lavender oil, menthol, methyl salicylate

Questions or comments? 1-877-586-7979

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Easton, MD 21601

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LAAPS01 Rev. 01/17

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

PEEL HERE THEN
TWIST TO OPEN



Aphena
Pharma Solutions

NDC 54884-050-01

NASAL DECONGESTANT INHALER

LEVMEAMFETAMINE

**TEMPORARY RELIEF OF
NASAL CONGESTION DUE TO:**

Colds • Hay fever

Upper Respiratory Allergies

NET WT .007 OZ (198 mg)

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

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NASAL DECONGESTANT INHALER

levmetamfetamine nasal decongestant inhalant

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54884-050
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVMEAMFETAMINE (UNII: Y24T9BT2Q2) (LEVMEAMFETAMINE - UNII:Y24T9BT2Q2)	LEVMEAMFETAMINE	50 mg

Inactive Ingredients

Ingredient Name	Strength
BORNYL ACETATE (UNII: 213431586X)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
MENTHOL (UNII: L7T10EP3A)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54884-050-01	1 in 1 BLISTER PACK	01/11/2017	
1		198 in 1 INHALER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2016	

Labeler - Aphenia Pharma Solutions (829739833)

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

Establishment

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Maryland, LLC		829739833	manufacture(54884-050) , pack(54884-050) , label(54884-050)

Revised: 1/2017

Aphenia Pharma Solutions