VAPOR INHALER LEVMETAMFETAMINE NASAL DECONGESTANT, EQUALINE - levmetamfetamine inhalant Supervalu 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

over	2 inhalations in each nostril
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?

1-877-932-7948

Principal Display Panel - 198 mg Blister Pack Label

NDC 41163-031-01

compare to **Original Vicks**® **VapoInhaler**®
active ingredient*

EQUALINE®

nasal decongestant

vapor inhaler

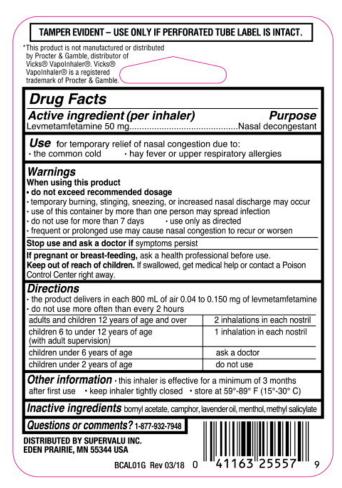
levmetamfetamine (nasal decongestant)

temporary relief of nasal congestion due to:

- colds hay fever
- upper respiratory allergies

NET WT .007 OZ (198mg)





Principal Display Panel - 198 mg Blister Pack Label EQUALINE®

NDC 41163-031-01

nasal decongestant

vapor inhaler

levmetamfetamine (nasal decongestant)

NET WT .007 OZ (198mg)

EQUALINE®

NDC 41163-031-01

nasal decongestant **vapor inhaler**levmetamfetamine (nasal decongestant)

NET WT.007 OZ (198mg)

Active ingredient (per inhaler)

Purpose

Use for temporary relief of nasal congestion due to: ■ colds ■ hay fever ■ 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 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°-89° F (15°-30° C)

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

Questions or comments? 1-877-932-7948

DISTRIBUTED BY SUPERVALU INC., EDEN PRAIRIE, MN 55344 USA

LAAL01E Rev. 03/18

LEVMETAMFETAMINE NASAL DECONGESTANT, VAPOR INHALER **EQUALINE**

levmetamfetamine inhalant

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41163-031

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	
NDC:41163-	1 in 1 BLISTER PACK	02/24/2021		
1	198 in 1 INHALER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)			

Marketing Information					
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date		
OTC monograph final	part341	02/24/2021			

Labeler - Supervalu Inc. (006961411)

Registrant - Aphena Pharma Solutions MD, LLC (829739833)

Establishment					
Name	Address	ID/FEI	Business Operations		
Aphena Pharma Solutions MD, LLC		829739833	MANUFACTURE(41163-031)		

Revised: 2/2023 Supervalu Inc.