

AMORAY PREMIUM VAPORIZING INHALER- menthol liquid
Ningbo Pulisi Daily Chemical Products Co.,Ltd.

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.

Active Ingredients

Menthol 5% Nasal Decongestant
camphor 13% Nasal Decongestant

Purpose

Nasal Decongestant

INDICATIONS:

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 AN INCREASED IN NASAL DISCHARGE may occur.
- THE USE OF THIS CONTAINER BY MORE THAN ONE PERSON MAY SPREAD INFECTION.
- DO NOT USE THIS PRODUCT FOR MORE THAN 7 DAY. USE ONLY AS DIRECTED.
- FREQUENT OR PROLONGED USE MAY CAUSE NASAL CONGESTION TO RECUR OR WORSEN.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. if swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

- THE PRODUCT DELIVERS IN EACH 800ML OF AIR 0.04 TO 0.150 MG OF LEVMETAMFETAMINE.
- Do not use more often than 2 hours.

ADULTS AND CHILDREN 12 YEARS OF AGE AND OVER: 2 INHALATIONS IN EACH NOSTRIL.

CHILDREN 6 TO 12 YEARS OF AGE (WITH ADULT SUPERVISION): 1 INHALATION IN EACH NOSTRIL.

CHILDREN UNDER 6 YEARS OF AGE: CONSULT A DOCTOR.

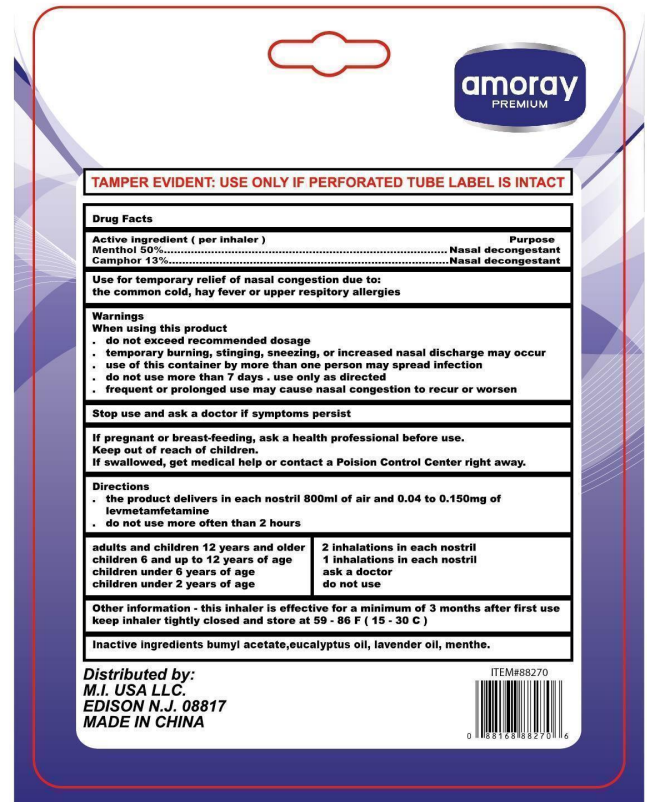
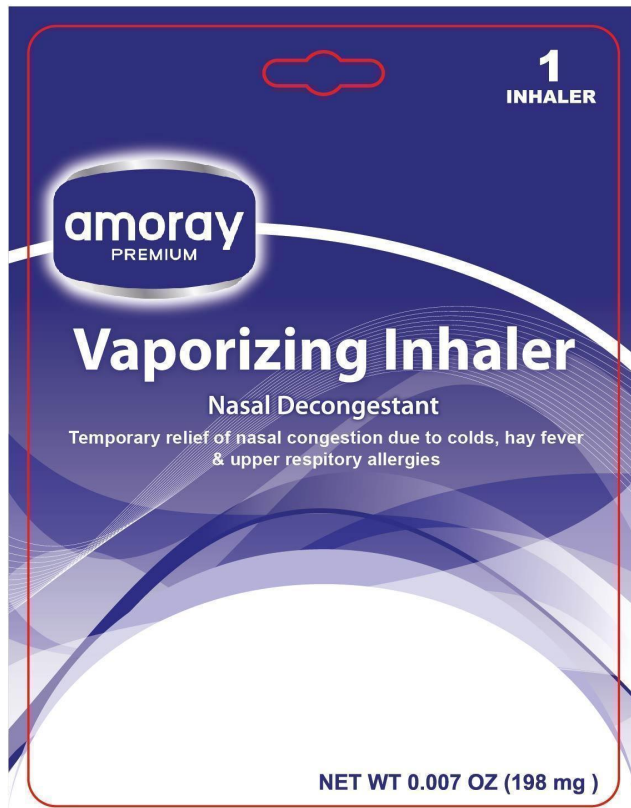
Childre nuder 2 years of age: DO NOT USE.

Inactive Ingredients:

BUMYL ACETATE, EUCALYTUS OIL, LAVENDER OIL, MENTHE

THIS INHALER IS EFFECTIVE FOR A MINIMUM OF 3 MONTHS AFTER FIRST USE. KEEP INHALER TIGHTLY CLOSED AND STORE AT 59-86 F (15-30 C)

90X119mm



AMORAY PREMIUM VAPORIZING INHALER

menthol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40104-800
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	13 mg

Inactive Ingredients

Ingredient Name	Strength
MENTHOL (UNII: L7T10EIP3A)	50 mg
EUCALYPTUS OIL (UNII: 2R04ONI662)	
BORNYL ACETATE (UNII: 213431586X)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40 104-800-01	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	03/31/2016	

Labeler - Ningbo Pulisi Daily Chemical Products Co.,Ltd. (529047265)

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Pulisi Daily Chemical Products Co.,Ltd.		529047265	manufacture(40 104-800)

Revised: 3/2016

Ningbo Pulisi Daily Chemical Products Co.,Ltd.