AMMONIA INHALANTS- ammonia inhalants inhalant Sina Health Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

AMMONIA INHALANTS

Active ingredient(s)

Ammonia (15%)

Purpose

Inhalant

Use(s)

To prevent or treat fainting

Warnings

Keep away from the Eyes.

For external use only

Stop use and ask a doctor if

condition persists

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Directions: hold inhalant away from face and crush between thumb and forefinger. Carefully approach crushed inhalant to nostrils of affected person.

Other information

Store at room temperature away from light.

Storage

Store at 20°C to 25°C (68°F to 77°F)

Inactive ingredients

Alcohol USP, FDC red dye 40, lavender oil fcc, lemon oil fcc, nutmeg oil fcc, purified water usp

Questions

Questions? Call 1-866-390-4411 Mon - Fri 9:00 AM - 5:00 PM

Principal Display Panel





Ammonia 15% Inhalant 0.33mL

To Prevent or Treat Fainting

Qty: 3

OTC

Lot # XXXXX

Exp Date: XX/XXXX

Keep Out of Reach of Children. Store at 68-77F (20-25C) See product insert for complete use and cautionary information

Mfr for XGen Pharmaceuticals, Inc., Northport, NY 11768

Mfr NDC: 39822-9900-1

AMMONIA INHALANTS

ammonia inhalants inhalant

Product Information

HUMAN PRESCRIPTION Product Type

DRUG

Item Code (Source)

NDC:70385-2003(NDC:39822-

9900)

Route of Administration

RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMMO NIA (UNII: 5138 Q 19 F1X) (AMMO NIA - UNII:5138 Q 19 F1X)	AMMONIA	0.045 g in 0.3 mL

Inactive Ingredients	
Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
LAVENDER O IL (UNII: ZBP1YXW0H8)	
WATER (UNII: 059QF0KO0R)	
NUTMEG OIL (UNII: Z1CLM48948)	
LEMON OIL (UNII: 19 GRO 8 2 4 L L)	

ı	Packaging				
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 N	NDC:70385-2003-3	3 in 1 BAG	04/18/2016	
ı	1		$0.33\ mL$ in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/14/1976	

Labeler - Sina Health Inc (047161553)

Registrant - Sina Health Inc (047191553)

Establishment				
Name	Address	ID/FEI	Business Operations	
Sina Health Inc		047161553	repack(70385-2003)	

Revised: 2/2019 Sina Health Inc