

ASTONEA COLD ICE ANALGESIC GEL- menthol gel
ASTONEA LABS PRIVATE LIMITED

Astonea Cold Ice Gel

Active Ingredient

Menthol 2.0%

Purpose

Topical Analgesic

Uses:

- for temporary relief of minor aches and pains in muscles and joints associated with:
- simple backaches,
- strains
- sprains
- sports injuries
- arthritis
- bruises

Warnings

FOR EXTERNAL USE ONLY

Do not use:

- with other topical pain relievers
- with heating pads or heating devices

When using this product

- do not use in or near eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days
- redness or irritation develops

If pregnant or breastfeeding

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

- clean affected area before applying product
- adults and children 2 years of age and older; apply to affected area not more than 3 to 4 times daily

Inactive Ingredients

ammonium hydroxide, carbomer, cupric sulfate, FD&C Blue No. 1, isopropyl alcohol, magnesium sulfate, sodium hydroxide, thymol, water

ASTONEA

Cold ICE
Analgesic Gel

Net Wt.:
8 oz. (227g)

Drug Facts

Active ingredients
Menthol, 2% w/w.....topical analgesic

Purpose
For the temporary relief of minor aches and pains in muscles and joints associated with:
 headache
 sprains
 arthritis
 sports injuries
 bruises

Uses
For external use only

Warnings
 Do not use with other topical pain relievers with heating pads or heating devices
 When using this product
 do not use in or near eyes
 do not apply to wounds or damaged skin
 do not bandage tightly

Stop use and ask a doctor if
 condition worsens
 symptoms last more than 7 days or clear up and occur again within a few days
 redness or irritation develops

If pregnant or breast-feeding,
ask a health professional before use.

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

Directions
 Clean affected area before applying product
 adults and children 2 years of age and older; apply to affected area not more than 3 to 4 times daily

Other information
 store at room temperature

Inactive ingredients
ammonium hydroxide, carbomer, cupric sulphate, FD&C blue No. 1, isopropyl alcohol, magnesium sulphate, sodium hydroxide, thymol, water

Manufactured by:
Vantage Therapeutics, Inc.
Vantage Therapeutics, Topical Healthcare
10000 Westpark Drive
Houston, Texas 77036
FDA - 141251
NADA 141-251
HFDX0131802 (09/14)

LOT NO.:
MFG. DATE:
EXP. DATE:

ASTONEA COLD ICE ANALGESIC GEL

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-402
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4.54 g in 227 g

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CUPRIC SULFATE (UNII: LRX7AJ16DT)	
THYMOL (UNII: 3J50XA376E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-402-12	227 g in 1 JAR; Type 0: Not a Combination Product	04/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	04/08/2019	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Revised: 6/2024

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