

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

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.

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

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 final	part341	04/08/2019	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Revised: 12/2022

ASTONEA LABS PRIVATE LIMITED