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

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							
Product Information								
Product Type	HUMAN OTC DRUG	ltem Co	de (Source)	NDC:77338-402				
Route of Administration	TOPICAL							
Active Ingredient/Active Moiety								
Ingredient Name			Basis of Strength	Strength				

In	active Ingree			
		Ingredient Name		Strength
AM	IMONIA (UNII: 513	38Q19F1X)		
ISC	OPROPYL ALCOH	OL (UNII: ND2M416302)		
CU	IPRIC SULFATE (UNII: LRX7AJ16DT)		
тн	YMOL (UNII: 3J50)	XA376E)		
FD	&C BLUE NO. 1	(UNII: H3R47K3TBD)		
WA	ATER (UNII: 059QF	FOKOOR)		
so	DIUM HYDROXID	DE (UNII: 55X04QC32I)		
CA	RBOMER HOMO	POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM	307FC)	
MA	GNESIUM SULFA	ATE, UNSPECIFIED (UNII: DE08037SAB)		
		(UNII: DE000373AB)		
Pa	ackaging			
		Package Description	Marketing Start Date	Marketing End Date
#	ackaging Item Code		-	
#	ackaging Item Code NDC:77338-402-	Package Description 227 g in 1 JAR; Type 0: Not a Combination	Date	
#	item Code NDC:77338-402- 12	Package Description 227 g in 1 JAR; Type 0: Not a Combination	Date	
#	item Code NDC:77338-402- 12	Package Description 227 g in 1 JAR; Type 0: Not a Combination Product	Date 04/08/2019	Date

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

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