

ASTONEA COLD THERAPY- menthol 4% gel
ASTONEA LABS PRIVATE LIMITED

ASTONEA COLD THERAPY 4% MENTHOL

Menthol 4%

Topical Analgesic

Temporary relief from minor aches and pains of sore muscles and joints associated with:
arthritis

backache

strains

sprains

For external use only

Flammable:Keep away from excessive heat or open flame

Ask a doctor before use if you have: sensitive skin

Stop use and ask a doctor if

condition worsens or symptoms persist for more than 7 days or clear up and occur again within a few days.

When using this product

■avoid contact with eyes or mucous membranes ■do not apply to wounds or damaged skin ■ do not use with other ointments, creams, sprays or liniments ■ do not apply to irritated skin or if excessive irritation develops ■do not bandage ■ wash hands after use with cool water ■do not use with heating pad or device

If pregnant or breastfeeding, ask a health professional before use

Keep out of reach of children: If accidentally ingested, get medical help or contact a poison Control immediately (1800-222-1222)

Directions

Adults and children 2 years of age and older:Rub a thin film over affected areas not more than daily: massage not necessary

Children under 2 years of age :Consult physician

camphor, carbopol 940, DMDM hydantoin, edetate disodium, FD&C yellow no. 5, FD&C blue no. 1, isopropyl alcohol, PEG 40

hydrogenated castor oil, propylene glycol, sodium hydroxide, water

ASTONEA

Cold Therapy Gel

Menthol 4%
Topical Analgesic

Pain Relieving Gel
For Arthritis, Backaches,
Joint & Muscle Pain
Soothing Menthol Scent

4 FL OZ (118.2ml)

Drug Facts

Active ingredient	Purpose
Menthol 4%	Topical analgesic

Uses Temporary relief from minor aches and pains of sore muscles and joints associated with:
■ arthritis ■ backache ■ strains ■ sprains

Warnings For external use only

Flammable: keep away from excessive heat or open flame

Ask a doctor before use if you have:
sensitive skin

When using this product: ■ avoid contact with eyes or mucous membranes ■ do not apply to wounds or damaged skin ■ do not use with other ointments, creams, sprays or liniments ■ do not apply to irritated skin or if excessive irritation develops ■ do not bandage ■ wash hands after use with cool water ■ do not use with heating pad or device

Stop use and ask a doctor if: condition worsens, if symptoms last more than 7 days or clear up and reoccur

If pregnant or breast feeding: ask a health professional before use

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Adults and children 2 years of age and older:

■ rub a thin film over affected area not more than 4 times daily, massage not necessary

Children under 2 years of age: consult physician

Other information ■ store in a cool dry place
■ do not use if tube seal under cap is broken

Inactive ingredients benzyl alcohol, camphor, carbopol 940, DMDM hydantoin, edetate disodium, FD&C yellow no. 5, FD&C blue no. 1, isopropyl alcohol, PEG 40 hydrogenated castor oil, propylene glycol, sodium hydroxide, water

Manufactured by: Astonea Labs Private Limited
Village Haripur, Tehsil Raipurani,
Near Mouli Police Station, Panchkula,
Haryana, India - 134204

Made in India

ASTONEA COLD THERAPY

menthol 4% gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT)	
GLYCERIN (UNII: PDC6A3C0OX)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-007-04	118.2 g in 1 TUBE; Type 0: Not a Combination Product	03/12/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/12/2024	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)