

PRIYAL COLD ICE ANALGESIC GEL- menthol gel

Priyal Cosmetics

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.

Priyal 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



Drug Facts

Active ingredients

Menthol 2%.....Topical analgesic

Purpose

Uses for the temporary relief of minor aches and pains in muscles and joints associated with:

- simple backache
- sprains
- arthritis
- strains
- sports injuries
- 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 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 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 sulphate, FD&C blue No.1, ..

isopropyl alcohol, magnesium sulphate, sodium hydroxide, thymol, water

Manufactured by
PRIYAL COSMETICS
167, Mahagujarat Industrial Estate,
Moraiya, Near Changodar, Taluk Sanand,
Ahmedabad - 382213, Gujarat, India

Made in India
GUJ/COS/GC/32/1275

LOT NO.:

EXP DATE:

PRIYAL COLD ICE ANALGESIC GEL

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72822-303
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
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CUPRIC SULFATE (UNII: LRX7AJ16DT)	
THYMOL (UNII: 3J50XA376E)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72822-303-12	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 - Priyal Cosmetics (675482356)

Revised: 7/2020

Priyal Cosmetics