

PRIYAL ICE GEL- menthol, camphor cream

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 Ice Gel

Camphor.....0.5 %

Menthol.....1.25 %

Menthol 1.25 %.....Topical Analgesic

Camphor 0.5 %.....Topical Analgesic

- 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
- Children under 2 years of age: ask a doctor

Uses:

temporarily relieves minor aches and pains of muscles and joints associated with:

- arthritis
- simple backache
- strains
- bruises
- sport injuries
- sprains

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

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 the 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

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

Aqua, Propylene Glycol, Carbomer, Methyl Salicylate, Sodium Hydroxide, Sodium Methyl Paraben, Sodium Propylene Paraben, FD&C Blue #1 CI 42090

Other information

- Store at room temperature 59-86 F (15-30 C)
- Keep jar tightly closed and away from open heat or flame

Purpose	Active Ingredients
Menthol 1.25%.....Topical Analgesic Camphor 0.5%.....Topical Analgesic	Menthol 1.25%.....Topical Analgesic Camphor 0.5%.....Topical Analgesic
Uses ■ for the temporary relief of minor aches and pains of muscles and joints associated with: ■ simple backache ■ strains ■ sprains ■ sports injuries ■ arthritis ■ bruises	
Warnings: For external use only	
Do not use ■ with other topical pain relievers ■ with heating pads or heating services	
When using this product ■ do not use in or near eyes ■ do not apply to wounds or damaged skin ■ do not repackage lightly	
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: Cachomer, FD&C Blue #1, Methyl Paraben Sodium, Methyl Salicylate, Propylene Glycol, Propyl Paraben Sodium, Sodium Hydroxide, Water.	

PRIYAL ICE GEL

menthol, camphor cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72822-016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	0.5 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
METHYL PARABEN SODIUM (UNII: CR6K9C2NHK)	
PROPYL PARABEN SODIUM (UNII: 625NNB0G9N)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72822-016-02	227 g in 1 JAR; Type 0: Not a Combination Product	01/26/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/26/2018	

Labeler - Priyal Cosmetics (675482356)

