

COLD AND HOT- menthol cream
MAGVERZ INC

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.

Cold and Hot Cream

Actives

Menthol 7.5%

Inactives

aloe barbadensis leaf juice, beeswax, benzyl alcohol, capsaicin, cetearyl alcohol, cetyl alcohol, cetyl esters, cetyl palmitate, citrus paradise (grapefruit) peel oil, di-PEG-2 soyamine IPDI, disodium LPDL, distearyldimonium chloride, eucalyptus globules leaf oil, glycerin, hydrogenated olive oil, jojoba esters, melaleuca alternifolia (tea tree) leaf oil, menthe viridis (spearmint) leaf oil, olea europaea (olive) fruit oil, olea europaea (olive) oil unsaponifiables, polysorbate 60, potassium hydroxide, propanediol, sorbitan olivate, sorbitan palmitate, steareth-2, steareth-21, stearyl alcohol, water

Uses

Temporarily relieves minor pain associated with:

arthritis

backache

bodyaches

muscle pains

leg cramps

bursitis

Indication

Temporarily relieves minor pain

Directions

Adults and children over 1 years: apply generously to affected area massage into painful area until thoroughly absorbed into skin repeat as necessary, but no more than 4 times daily.

Children 12 years or younger: ask a doctor.

Close cap tightly after use.

Warnings

For External use only

When using this product

Use only as directed

Do not bandage tightly or with heating pad

Avoid contact with eyes and mucous membranes

Do not apply to wounds or damaged, broken or irritated skin

Do not expose the area treated with product to heat or direct sunlight.

Stop use and ask doctor if;

Condition Worsens, Symptoms persist for more than 7 days or clear up and occur again within a few days, Irritation develops.

If pregnant or breast feeding

Ask health professionals before use.

If swallowed get medical help or contact poison control center right away.

Keep Out of Reach of Childrens

Keep out of reach of childrens.

Productt Label

Product Label

Other information Store at controlled room temperature 15°c to 30° c (59°F to 86 °F)

Inactive ingredients Aloe Barbadensis Leaf Juice, Beeswax, Benzyl Alcohol, Capsaicin; Cetearyl Alcohol; Cetyl Alcohol; Cetyl Esters; Cetyl Palmitate; Citrus Paradisi (Grapefruit) Peel Oil; Di-PEG-2 Soyamine LPDL; Disodium EDTA; Distearyltrimonium Chloride; Eucalyptus Globulus leaf Oil; Glycerin; Hydrogenated Olive Oil; Jojoba Esters; Melaleuca Alternifolia (Tea Tree) Leaf Oil; Mentha viridis (Spearmint) Leaf Oil; olea Europaea (Olive) fruit Oil; Olea Europaea (Olive) oil Unsaponifiables; Polysorbate 60; Potassium Hydroxide; Propanediol; Sorbitan Oliviate; Sorbitan Palmitate; Steareth-2; Steareth-21; Stearyl Alcohol; Water

This product is not manufactured or distributed by Chattem Inc, owner of the registered trademark Icy Hot Naturals,
 Distributed by :**MAGVERZ INC** SANTA MONICA CA, 90401, USA

Lot:
Exp:



Drugs Facts

Active Ingredients

Menthol 7.5%

Purpose

Topical analgesic

Uses temporary relieves minor pain associated with: arthritis backache body aches muscle pains leg cramps bursitis.

Warnings

For external use only

When using this product use only as directed do not bandage lightly or use with a healing pad avoid contact with eyes or mucous membranes do not apply to wounds or damaged, broken or irritated skin do not expose the area treated with product to heat or direct sunlight.

Stop use and ask a doctor if. condition worsen symptoms persist for more than 7 days or clear up and occur again within a few days redness is present irritation develops

If pregnant or breast-feeding, ask a health professional before using.

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a poison control center right away.

Directions

Adults and children over 12 years: apply generously to affected area massage into painful area until thoroughly absorbed into skin repeat as necessary, but no more than 4 times daily.

Children 12 years or younger: ask a doctor. close cap tightly after use.

PRODUCT OF INDIA

COLD AND HOT

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59240-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.075 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

YELLOW WAX (UNII: 2ZA36H0S2V)
BENZYL ALCOHOL (UNII: LKG8494WBH)
CAPSAICIN (UNII: S07O44R1ZM)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETYL ALCOHOL (UNII: 936JST6JCN)
CETYL ESTERS WAX (UNII: D072FFP9GU)
CETYL PALMITATE (UNII: 5ZA2S6B08X)
CITRUS PARADISI FRUIT OIL (UNII: 6A7N43E0OJ)
EDETATE DISODIUM (UNII: 7FLD91C86K)
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)
EUCALYPTUS OIL (UNII: 2R04ONI662)
GLYCERIN (UNII: PDC6A3C0OX)
OLIVE OIL (UNII: 6UYK2W1W1E)
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)
SPEARMINT (UNII: J7I2T6IV1N)
POLYSORBATE 60 (UNII: CAL22UVI4M)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
PROPANEDIOL (UNII: 5965N8W85T)
SORBITAN OLIVATE (UNII: MDL271E3GR)
PEG-80 SORBITAN PALMITATE (UNII: 4NR71FN0IA)
STEARETH-2 (UNII: V56DFE46J5)
STEARETH-21 (UNII: 53J3F32P58)
STEARYL ALCOHOL (UNII: 2KR89I4HIY)
WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59240-003-01	25 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/18/2013	

Labeler - MAGVERZ INC (078712269)

Registrant - MAGVERZ INC (078712269)