

**ICY HOT WITH LIDOCAINE PAIN RELIEVING- lidocaine hcl and menthol cream
Chattem, Inc.**

Icy Hot Cream

***ICY HOT® with LIDOCAINE
PAIN RELIEVING CREAM
Drug Facts***

Active Ingredients

Lidocaine HCl 4%

Purposes

Topical anesthetic

Active Ingredients

Menthol 1 %

Purposes

Topical analgesic

Use

for the temporary relief of pain

Warnings

For external use only

Do not use

- in large quantities
- on wounds or on irritated or damaged skin
- with a heating pad

When using this product

- use only as directed
- do not bandage tightly

- avoid contact with eyes and mucous membranes
- do not expose the area to local heat or to direct sunlight
- rare cases of serious burns have been reported with products of this type
- a transient burning sensation may occur upon application but generally disappears in several days
- avoid applying into skin folds

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- redness is present or excessive skin irritation occurs
- you experience severe burning pain, swelling, or blistering where the product was applied

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children and pets.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years of age and older:
 - apply a thin layer to affected area every 6 to 8 hours, not more than 3 to 4 times daily
 - massage until thoroughly absorbed into skin
 - wash hands thoroughly with soap and water after each use
- children under 12 years of age: ask a doctor

Inactive ingredients

acrylates/C10-30 alkyl acrylate crosspolymer, alcohol denat. (15%), aloe barbadensis leaf juice, aminomethyl propanol, C30-45 alkyl cetearyl dimethicone crosspolymer, caprylyl methicone, cetearyl alcohol, ceteth-20 phosphate, dicetyl phosphate, dimethicone, disodium EDTA, ethylhexylglycerin, glyceryl stearate, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, isohexadecane, methylparaben, polysorbate 60, steareth-21, water

Keep Carton As It Contains Important Information

Close cap tightly between uses.

PRINCIPAL DISPLAY PANEL

ICY HOT
MAX
LIDOCAINE
PAIN RELIEF CREAM
Net Wt 2.7 OZ (76.5 g)



ICY HOT WITH LIDOCAINE PAIN RELIEVING

lidocaine hcl and menthol cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41167-1710 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 0.4 g in 1 g |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 0.1 g in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------------|----------|
| ALCOHOL (UNII: 3K9958V90M) | |

| |
|--|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) |
| C30-45 ALKYL CETEARYL DIMETHICONE CROSSPOLYMER (UNII: 4ZK9VP326R) |
| CAPRYLYL METHICONE (UNII: Q95M2P1KJL) |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) |
| CETETH-20 PHOSPHATE (UNII: 921FTA1500) |
| DICETYL PHOSPHATE (UNII: 2V6E5WN99N) |
| DIMETHICONE (UNII: 92RU3N3Y1O) |
| EDETATE DISODIUM (UNII: 7FLD91C86K) |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) |
| GLYCERYL STEARATE (UNII: 230OU9XXE4) |
| HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4) |
| ISOHEXADECANE (UNII: 918X1OUF1E) |
| METHYLPARABEN (UNII: A2I8C7HI9T) |
| POLYSORBATE 60 (UNII: CAL22UVI4M) |
| STEARETH-21 (UNII: 53J3F32P58) |
| WATER (UNII: 059QF0KO0R) |
| ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S AT 1.0%) (UNII: 8Z5ZAL5H3V) |

| Packaging | | | | |
|------------------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:41167-1710-2 | 1 in 1 CARTON | 03/01/2016 | |
| 1 | | 49.6 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:41167-1710-0 | 1 in 1 CARTON | 03/01/2016 | |
| 2 | | 76.5 g in 1 TUBE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M017 | 03/01/2016 | |

Labeler - Chattem, Inc. (003336013)