MENTHOLATUM LIDOCAINE ICE- lidocaine hcl, menthol gel
The Mentholatum Company

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.

Drug Facts

Active ingredients

Lidocaine HCl 4%

Menthol 1%

Purpose

Lidocaine HCl - Topical anesthetic

Menthol – Topical analgesic

Uses

temporarily relieves pain

Warnings

For external use only

Do not use

- on large areas of the body or on cut, irritated or blistered skin
- on puncture wounds
- for more than one week without consulting a doctor

When using this product

- use only as directed
- do not get into eyes
- do not bandage tightly or apply external heat to the area of use

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness, rash, or irritation occurs

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

- adults and children 12 years and over: apply a thin layer to affected area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period
- children under 12 years: ask a doctor

Inactive ingredients

acrylates/C10-30 alkyl acrylate crosspolymer, alcohol, aloe barbadensis leaf juice, aminomethyl propanol, bis-vinyl dimethicone/dimecthicone copolymer, C30-45 alkyl cetearyl dimethicone crosspolymer, caprylyl methicone, cetearyl alcohol, ceteth-20 phosphate, chlorphenesin, dicetyl phosphate, dimethicone, edetate disodium, ethoxydiglycol, glycerin, glyceryl monostearate, methoxypropanediol, phenoxyethanol, purified water, steareth-21

Package/Label Principal Display Panel

MENTHOLATUM LIDOCAINE ICE

lidocaine hcl, menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10742-1389
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	40 mg in 1 mL
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALCOHOL (UNII: 3K9958V90M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-20 PHOSPHATE (UNII: 921FTA1500)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERIN METHYL ETHER (UNII: 42ESM1DR47)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	
STEARETH-21 (UNII: 53J3F32P58)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-1389-1	1 in 1 CARTON	08/01/2018	
1		80 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/01/2018	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-1389)

Revised: 2/2023

The Mentholatum Company