MENTHOLATUM LIDOCAINE HEAT- lidocaine hcl cream
The Mentholatum Company

Drug Facts - Mentholatum Lidocaine Heat

Active ingredients

Lidocaine HCl 4%

Purpose

Lidocaine HCl - Topical anesthetic

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/dimethicone copolymer, C30-45 alkyl cetearyl dimethicone crosspolymer, caprylyl methicone, cetearyl alcohol, ceteth-20 phosphate, chlorphenesin, dicetyl phosphate, dimethicone, edetate disodium, glycerin, glyceryl monostearate, phenoxyethanol, polysorbate 20, purified water, steareth-21, vanillyl butyl ether

Package/Label Principal Display Panel

MENTHOLATUM LIDOCAINE HEAT

lidocaine hcl cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10742-8386
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE -	LIDOCAINE HYDROCHLORIDE	40 mg

UNII:98PI200987)	ANHYDROUS	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)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	
STEARETH-21 (UNII: 53J3F32P58)	
VANILLYL BUTYL ETHER (UNII: S2ULN37C9R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-8386-1	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 Drug	M017	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(10742-8386)