ZYLOTROL PAIN RELIEVING- lidocaine hcl, menthol cream
Asclemed USA, Inc.

ZYLOTROL PAIN RELIEVING CREAM

Drug Facts

Active ingredients

Lidocaine HCl 4.0%

Menthol 1.0%

Purpose

Topical Analgesic, Anesthetic

Uses

For temporarily relief of pain

Warnings

For external use only.

Ask a doctor before use if you have a heart condition.

Do not use •if you are allergic to any other type of numbing medicine •in large quantities, particularly over raw surfaces or blistered areas •on infections •on deep puncture wounds •if pregnant or breastfeeding.

When using this product •do not use over large skin areas •do not apply heat, bandages or plastic wrap to treated areas •do not use in or near the eyes •wash hands immediately after using.

Stop use and ask a doctor if •allergic reaction occurs •condition worsens or does not improve within 7 days •symptoms clear up and return within a few days •redness, irritation, swelling, pain or other symptoms begin or increase.

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

Directions

Apply generously up to 3 to 4 times daily. For use on adults and children 12 years and older. Children under 12 - ask a doctor.

Inactive ingredients:

Allantoin, Aloe Barbadensis Leaf Juice*, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Arnica Montana Flower Extract, Behenyl Alcohol, Boswellia Serrata Extract, Butyrospermum Parkii (Shea) Butter, Calophyllum Inophyllum (Tamanu) Seed Oil, Caprylic/capric Triglyceride, Ceteareth-20, Cetearyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Ethylhexylglycerin, Hypericum Perforatum (St. John's Wort) Flower/leaf/stem Extract, Glyceryl Stearate, Glycerin, Hydrogenated Polydecene, Isopropyl Palmitate, Peg-100 Stearate, Persea Gratissima (Avocado) Oil, Phenoxyethanol, Polysorbate 60, Propanediol, Sodium Polyacrylate, Stearyl Alcohol, Tetrahydroxypropyl Ethylenediamine, Trideceth-6, Water.

*Certified Organic Ingredient - Mayacert Certifier

Questions?

(310) 320-0100

Label

ZYLOTROL PAIN RELIEVING

lidocaine hcl, menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76420-560(NDC:81902-230)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL -	MENTHOL, UNSPECIFIED FORM	1 g

UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
PROPANEDIOL (UNII: 5965N8W85T)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
DOCOSANOL (UNII: 9G1OE216XY)	
EDETOL (UNII: Q4R969U9FR)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ALLANTOIN (UNII: 344S277G0Z)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
TAMANU OIL (UNII: JT3LVK84A1)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CHAMOMILE (UNII: FGL3685T2X)	
ST. JOHN'S WORT (UNII: UFH8805FKA)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76420-560-04	102 g in 1 TUBE; Type 0: Not a Combination Product	05/15/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	12/29/2022	

Labeler - Asclemed USA, Inc. (059888437)

Establishment

Name	Address	ID/FEI	Business Operations
ASCLEMED USA INC. DBA ENOVACHEM		059888437	relabel(76420-560)

Revised: 10/2023 Asclemed USA, Inc.