

**ZYLOTROL- lidocaine hcl 4%, menthol 1% gel**  
**Asclemed USA, Inc.**

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**Zylotrol**

***Active Ingredients***

Lidocaine HCl 4%

Menthol 1%

***Purpose***

Topical Analgesic

***Uses***

For the temporary relief of pain.

***Warnings***

**For external use only** not intended for ingestion.

**Do not use**

- in large quantities, particularly over raw surfaces, or blistered areas.

**When using this product**

- Avoid contact with the eyes.

**Stop use and ask a doctor if**

- condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

**Keep out of reach of children.**

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

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

***Directions***

- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times a daily.
- Children under 2 years of age: consult a doctor.

***Other information***

- Store at 20-25 °C (68-77 °F) and protect from moisture.

***Inactive ingredients***

Aloe Barbadosis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Carbomer, Ethylhexylglycerin, Isopropyl Alcohol, Phenoxyethanol, Triethanolamine.

***Questions?***

(310) 320-0100

**Relabeled by:**  
 Enovachem PHARMACEUTICALS  
 Torrance, CA 90501

Packaged By:



**Zylotrol Gel**  
 NDC: 76420-145-04

Qty: 118.3



Distributed By: Whitestone Products LLC  
 Source NDC: 81902-201-04  
 Description: Lidocaine HCL 4%, Menthol 1%; topical analgesic gel  
 Lot #: 00000000 Exp:  
 Batch #: 00000000  
 Drug Status: OTC



(01) 0 0376420 14504 2  
 (17)  
 (10) 00000000  
 (21)

Zylotrol Gel  
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CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].

## ZYLOTROL

lidocaine hcl 4%, menthol 1% gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76420-145(NDC:81902-201)
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>INDIAN FRANKINCENSE</b> (UNII: 4PW41QCO2M)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76420-145-04	1 in 1 BOX	06/12/2022	
1		118.3 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	06/12/2022	

**Labeler** - Asclemed USA, Inc. (059888437)**Establishment**

Name	Address	ID/FEI	Business Operations
ASCLEMED USA INC. DBA ENOVACHEM		059888437	relabel(76420-145)

Revised: 10/2023

Asclemed USA, Inc.