**ZYLOTROL- lidocaine hcl 4%, menthol 1% gel**
**Whitestone Products LLC**

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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 symtoms 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 $^{O}$C (68-77 $^{O}$F) and protect from moisture.

***Inactive ingredients***

Aloe Barbadensis 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


# ZYLOTROL

lidocaine hcl 4%, menthol 1% gel

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:81902-201 |
| **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, UNSPECIFIED FORM - UNII:L7T10EIP3A) | MENTHOL, UNSPECIFIED FORM | 1 g in 100 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **ARNICA MONTANA FLOWER** (UNII: OZ0E5Y15PZ) | |
| **INDIAN FRANKINCENSE** (UNII: 4PW41QCO2M) | |

| | |
|---|---|
| **CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE** (UNII: 0A5MM307FC) | |
| **ETHYLHEXYLGLYCERIN** (UNII: 147D247K3P) | |
| **ISOPROPYL ALCOHOL** (UNII: ND2M416302) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **TROLAMINE** (UNII: 9O3K93S3TK) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:81902-201-04 | 1 in 1 BOX | 01/04/2022 | |
| **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 | 01/04/2022 | |

## Labeler - Whitestone Products LLC (118064415)

Revised: 10/2023 Whitestone Products LLC