

LIDOCAINE NUMBING CREAM- lidocaine cream
ONE2ZEE LIMITED LIABILITY 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.

Lidocaine Numbing Cream topical anesthetic cream with vitamin E

DRUG FACTS:

Active Ingredient:

Lidocaine HCl 5.0%

Purpose

- External Analgesic

Uses:

For the temporary relief of pain and discomfort associated with anorectal disorders.

Warnings:

- **For external use only.** If condition worsens or does not improve within 7 days, consult a doctor.

When using this product,

- Do not exceed the recommended daily dosage unless directed by a doctor.
- In case of bleeding, consult a doctor promptly.
- Do not put this product into the rectum by using fingers or any mechanical device or applicator.
- Keep out of reach of children.
- If swallowed, get medical help or contact the Poison Control Center immediately.
- If pregnant or breast feeding, ask a health professional before use.

Directions:

Children under 12: Consult a doctor.

Adults and children 12 years and older: For optimum results cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a clean, soft cloth before application of this product. Apply externally up to 6 times per day.

Keep out of reach of children.

Inactive Ingredients

Benzyl Alcohol, Carbomer 940, Cholesterol, Hydrogenated Lecithin, Isopropyl Myristate, Polysorbate 80, Propylene Glycol, Purified Water, Trolamine and Vitamin E Acetate

Other Information:

Store at room temperature. Avoid direct sunlight. Do not use if tamper evident packaging has been breached or is missing. See bottom of this jar for lot number and expiry date.

Distributed by: Wellspring Airmont, NY 10952 U.S.A.

Packaging label

<p>Drug Facts</p> <p>Active Ingredients Lidocaine (3% w/w)</p> <p>Purpose External Anesthetic</p> <p>Uses For the temporary relief of pain and discomfort associated with anorectal disorders.</p> <p>Warnings For external use only. If condition worsens or does not improve within 7 days, consult a doctor. Do not exceed the recommended daily dosage unless directed by a doctor. In case of bleeding, consult a doctor promptly. Do not put this product into the rectum by using fingers or any mechanical device or applicator. Keep out of reach of children. If swallowed, get medical help or contact the Poison Control Center immediately. If pregnant or breast feeding, ask a health professional before use.</p>	<p>Strongest non-prescription lidocaine</p> <p>Lidocaine Numbing Cream topical anesthetic cream with vitamin E</p> <p>5% lidocaine works faster lasts longer</p> <p>5.5oz VALUE SIZE</p> <p>welmate™ child resistant packaging 5.5oz 156g</p>	<p>Drug Facts (continued)</p> <p>Directions Children under 12: Consult a doctor. Adults and children 12 years and older: For optimum results cleanse the affected area with mild soap and warm water and rinse thoroughly, gently dry by patting or blotting with toilet tissue or a clean, soft cloth before application of this product. Apply externally up to 6 times per day.</p> <p>Inactive Ingredients Benzyl Alcohol, Carbomer 940, Cholesterol, Hydrogenated Lecithin, Isopropyl Myristate, Polysorbate 80, Propylene Glycol, Purified Water, Trolamine and Vitamin E Acetate</p> <p>Other Information Store at room temperature. Avoid direct sunlight. Do not use if tamper evident packaging has been breached or is missing. See bottom of this jar for lot number and expiry date.</p>	<p>Distributed by: Wellspring Airmont, NY 10952 U.S.A.</p> <p>Why pay more? wellspringmeds.com</p> <p>Lic# UK/Drugs/39/UA/2016</p>
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LIDOCAINE NUMBING CREAM

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55629-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

WATER (UNII: 059QF0KO0R)

TROLAMINE (UNII: 9O3K93S3TK)

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55629-050-55	156 mL in 1 JAR; Type 0: Not a Combination Product	06/14/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	06/14/2022	

Labeler - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

Registrant - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

Establishment

Name	Address	ID/FEI	Business Operations
YASH PHARMACEUTICALS		871409551	manufacture(55629-050)

Revised: 6/2022

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