

FORMULA 2 SKIN CARE- lidocaine 5% cream
Derma Care Research Labs

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.

Rectal Care

Lidocaine 5.0%

Local Anesthetic

Uses

Helps relieve the pain, itching, and burning associated with hemorrhoids and other anorectal disorders.

For external use only.

When using this product avoid contact with eyes, do not exceed recommended dosage unless directed by a doctor, do not put this product into the rectum by using fingers or any mechanical device or applicator.

Stop use and ask a doctor if rectal bleeding occurs, condition worsens or does not improve within 7 days, allergic reaction occurs to ingredients in this product, symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, or symptoms clear up and return within a few days.

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

- When practical, clean area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before applying.
- Adults and children 12 years and older: apply externally to the affected area up to 6 times a day.
- Children under 12 years of age: consult a doctor.
- To use finger cots: roll one finger cot over a finger. Gently squeeze cream onto finger cot. Smooth a layer of the cream over the affected area

Benzyl Alcohol, Carbomer, Cholesterol, Hydrogenated Lecithin, Isopropyl Myristate, Polysorbate 80, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water

**Formula 2
SKIN CARE**

Rectal Care Cream



Developed by
a pharmacist
with 30 years
of experience.

Highest Non-Rx Lidocaine Strength Available

Relieves Pain ■ Relieves Itching ■ Relieves Burning

PHARMACIST FORMULATED

NDC 72839-265-00

LIDOCAINE 5%

**Formula 2
SKIN CARE**



Developed By
A Pharmacist.

Rectal Care Cream

Rapid Pain Relief for Hemorrhoids
& Other Anorectal Disorders

Net Wt 1.0 OZ (28 g)

10 Finger
Cots
INCLUDED



Drug Facts

Active ingredient

Lidocaine 5.0%

Purpose

Local anesthetic

Uses Helps relieve the pain, itching and burning associated with hemorrhoids and other anorectal disorders.

Warnings

For external use only.

When using this product ■ avoid contact with eyes ■ do not exceed recommended dosage unless directed by a doctor ■ do not put this product into the rectum →

Drug Facts (continued)

by using fingers or any mechanical device or applicator.

Stop use and ask a doctor if ■ rectal bleeding occurs ■ condition worsens or does not improve within 7 days ■ allergic reaction occurs to ingredients in this product ■ symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase ■ symptoms clear up and return within a few days.

If pregnant or breastfeeding, 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. ↓

Drug Facts (continued)

Directions

- When practical, clean area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or soft cloth before applying.
- Adults and children 12 years and older: apply externally to the affected area up to 6 times a day.
- Children under 12 years of age: consult a doctor.
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Drug Facts (continued)

Other information

Store at 15-30° C (57-86° F).

Inactive ingredients

Benzyl Alcohol, Carbomer, Cholesterol, Hydrogenated Lecithin, Isopropyl Myristate, Polysorbate 80, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water.

Questions? (833) 322-7326

Distributed by: MSI Enterprises, Inc.
Avondale, PA 19311

www.f2skincare.com

FORMULA 2 SKIN CARE

lidocaine 5% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72839-265
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HO MO POL YMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
HYDROGENATED SO YBEAN LECITHIN (UNII: H1109Z9J4N)	

ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
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:72839-265-00	28 g in 1 TUBE; Type 0: Not a Combination Product	03/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	03/09/2020	

Labeler - Derma Care Research Labs (116817470)

Registrant - Derma Care Research Labs (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs		116817470	manufacture(72839-265)

Revised: 3/2020

Derma Care Research Labs