

ZEROPAIN 5- topical anesthetic cream cream
Blackbull Store LLC

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.

Black Bull Lidocaine 5% cream

Active Ingredient(s)

Lidocaine HCl 5%

Purpose

Topical Anesthetic

Use

Anesthetic anorectal Cream For the temporary relief of pain and itching due to anorectal disorders

Warnings

For external use only.

Avoid contact with eyes.

Not for prolonged use.

Do not use in large quantities, particularly over raw surfaces or blistered areas.

Keep out of reach of children. If swallowed, get medical help, or contact a Poison Control Center right away +1 800-222-1222

Stop Use and Ask a Doctor if the condition worsens ■ symptoms persist for more than seven days or clear up and occur again within a few days. Rash or irritation develops, persists, or increases. If pregnant or breastfeeding, ask a health professional before use.

Directions

Adults and children 2 years old and older Clean the affected area Apply to affected area not more than 3 to 4 times daily Remove residue if desired Children under 2 years old: Consult a doctor

Other information

Store at 15 to 30°C (59 to 86°F) Tamper Evident: DO NOT USE IF SEAL ON TUBE IS

PUNCTURED OR MISSING

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Alcohol, Aloe Barbadensis Leaf Juice, Cetearyl Alcohol, Ceteth-10 Phosphate, Cyclopentasiloxane, Denatonium Benzoate, Dicyl Phosphate, Dimethicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Disodium EDTA, Ethylhexylglycerin, Gyceryl Stearate, Isohexadecane, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Maltodextrin, Phenoxyethanol, Simmondsia Chinensis (Jojoba) Seed Oil, Steareth-21, Tocopheryl Acetate, Water.

Call: (505) 800 6309 www.Zero-Pain.com

Package Label - Principal Display Panel

NUMBS SKIN FAST

ZEROPAIN

LIDOCAINE 5%

TOPICAL ANESTHETIC CREAM

ANORECTAL CREAM





WITH ALOE - JOJOBA OIL - VITAMIN E INFUSED | NT WT 2 OZ (57 GR)

DRUG FACTS

ACTIVE INGREDIENT: Lidocaine 5 %Topical Anesthetic anorectal Cream	DIRECTIONS: Adults and children 2 years old and older ■ Clean the affected area ■ Apply to affected area not more than 3 to 4 times daily ■ Remove residue if desired ■ Children under 2 years old: Consult a doctor
USE: For the temporary relief of pain and itching due to anorectal disorders.	OTHER INFORMATION: ■ Store at 15 to 30°C (59 to 86°F) ■ Tamper Evident: DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING
WARNINGS: For external use only. Avoid contact with eyes. Not for prolonged use. Do not use in large quantities, particularly over raw surfaces or blistered areas.	INACTIVE INGREDIENTS: Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Alcohol, Aloe Barbadensis Leaf Juice, Cetearyl Alcohol, Ceteth-10 Phosphate, Cyclopentasiloxane, Denatonium Benzoate, Dicyl Phosphate, Dimethicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Disodium EDTA, Ethylhexylglycerin, Gyceryl Stearate, Isohexadecane, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Maltodextrin, Phenoxyethanol, Simmondsia Chinensis (Jojoba) Seed Oil, Steareth-21, Tocopheryl Acetate, Water.
STOP USE AND ASK A DOCTOR IF: ■ Condition worsens ■ symptoms persist for more than 7 days or clears up and occurs again within a few days ■ Rash or irritation develops, persists, or increases.	Questions or Comments? (505) 800 6309 www.Zero-Pain.com NDC See Outer Box.
Keep out of reach of children If pregnant or breast-feeding, ask a health professional before use. If swallowed, get medical help, or contact a Poison Control Center right away. •1 505-800-6309	

ZEROPAIN

Distributed by
Blackbull Store LLC
8600 NW 64St
Miami - FL

2 OZ Cream, NDC: 83371-111-11

ZEROPAIN 5

topical anesthetic cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83371-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z 41A) (LIDOCAINE -	LIDOCAINE HYDROCHLORIDE	5 mg

UNII: 98PI200987)		ANHYDROUS		in 100 mL
Inactive Ingredients				
Ingredient Name				Strength
STEARETH-21 (UNII: 53J3F32P58)				
ISOHEXADECANE (UNII: 918X1OUF1E)				
ALCOHOL 95% (UNII: 7528N5H79B)				
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
WATER (UNII: 059QF0KO0R)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
DENATONIUM BENZOATE ANHYDROUS (UNII: M5BA6GAF1O)				
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)				
JOJOBA OIL (UNII: 724GKU717M)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)				
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)				
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)				
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83371-111-11	57 mL in 1 TUBE; Type 0: Not a Combination Product	05/31/2023	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		M015	05/31/2023	

Labeler - Blackbull Store LLC (085247371)