OPHYTE TATTOO NUMBING CREAM- numbing cream cream Changsha Beiliang E-commerce Co., Ltd

83887-002

Active Ingredient

Lidocaine 5%

Purpose

Local Anesthetic

Use

For temporary relief of local and anorectal itching, discomfort, and inflammation associated with anorectal disorders.

For temporary relief of pain, burning, and soreness.

Warnings

If symptoms worsen or do notimprove within 7 days, seek medicaadvice. Do not exceed the recommendeodaily dosage without doctor's instruction. Consult a doctor immediately if bleeding occurs. Do not insert this product into the rectum using fingers or any applicator. Some people may be allergic to the ingredients.Discontinue use and consult a doctor if symptoms persist or worsen,including redness, irritation, swelling, or pain. Note: Discontinue use and consult a doctor if symptoms persist or worsen, including redness, irritation. swelling, or pain due to possible

allergies to product ingredients

Do not use

Some people may be allergic tothe ingredients. Discontinue use and consult a doctor if symptoms persistor worsen, including rednessirritation, swelling, or pain.

When Using

When Using

If symptoms worsen or do not improve within 7 days, seek medicaladvice.Do not

exceed the recommended daily dosage without doctor'sinstruction.Consult a doctor immediately if bleeding occurs.

Do not insert this product into the rectum using fingers or any applicator. Some people may be allergic to the ingredients. Discontinue use and consult a doctor if symptoms persistor worsen, including redness, irritation, swelling, or pain.

Stop Use

Discontinue use and consult adoctor if symptoms persist orworsen, including redness, irritation, swelling, or pain due to possibleallergies to product ingredients.

Ask Doctor

Discontinue use and consult a doctor if symptoms persist or worsen, including redness, irritation. swelling, or pain due to possible allergies to product ingredients

Keep Oot Of Reach Of Children

This package is child-resistant.Keep out of reach of children

Directions

Adults: When practical, cleanse theaffected area with mild soap andwarm water, and rinse thoroughlyGently dry by patting or blotting withtoilet tissue or a soft cloth beforeapplication of this product.

Other information

Keep away from direct sunlight orheat. Store at room temperaturebetween 15°C and 30°C(59°F-86°F). This package is child-resistant.Keep out of reach of children. In case of accidental overdose oringestion, call a doctor or poisoncontrol center immediately. Do not use this product if the sealis broken or missing.

Inactive ingredients

Vitamin E Allantoin, Mineral Oil.Dimethicone,MethylparabenPropylparaben, Petrolatum, IPBCDiazolidinyl Urea, Glycerin,Cetostearyl Alcohol, IsopropylMyristate, Propylene Glycol,Ammonium,Methacrylate, PurifiedWater, Laurocapram, Steareth-2.Steareth-21 Rose Oil

PRINCIPAL DISPLAY PANEL









OPHYTE TATTOO NUMBING CREAM						
numbing cream cream						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code	e (Source)	NDC:	83887-002	
Route of Administration	TOPICAL					
Active Ingredient/Active Moiety						
Ingredient Name			Basis of Strength		Strength	
LIDOCAINE (UNII: 98PI200987) (LI	DOCAINE - UNII:98PI200987)		LIDOCAINE		5 g in 100 g	
Inactive Ingredients						
	Ingredient Name				Strength	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
ALLANTOIN (UNII: 344S277G0Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
ROSE OIL (UNII: WUB68Y35M7)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
AMMONIUM METHACRYLATE (UNII: J2243103QO)	
STEARETH-2 (UNII: V56DFE46J5)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
PETROLATUM (UNII: 4T6H12BN9U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LAUROCAPRAM (UNII: 1F3X9DRV9X)	
.ALPHATOCOPHEROL (UNII: H4N855PNZ1)	
WATER (UNII: 059QF0KO0R)	
STEARETH-21 (UNII: 53J3F32P58)	

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83887-002- 01	30 g in 1 TUBE; Type 0: Not a Combination Product	12/22/2023	
2	NDC:83887-002- 02	50 g in 1 BOTTLE; Type 0: Not a Combination Product	12/22/2023	
3	NDC:83887-002- 03	60 g in 1 BOTTLE; Type 0: Not a Combination Product	12/22/2023	
4	NDC:83887-002- 04	100 g in 1 BOTTLE; Type 0: Not a Combination Product	12/22/2023	
Marketing Information				

Category Citation Date	tart Marketing End Date
OTC Monograph Drug M017 12/22/2023	

Labeler - Changsha Beiliang E-commerce Co., Ltd (632138945)

Establishment					
Name	Address	ID/FEI	Business Operations		
Changsha Beiliang E-commerce Co., Ltd		632138945	label(83887-002) , manufacture(83887-002)		

Revised: 12/2023

Changsha Beiliang E-commerce Co., Ltd