

SAMNYTE TATTOO NUMBING CREAM- lidocaine emulsion
Sainite Trading Shenzhen Co., Ltd.

82929-010-(01,02,03)

Active Ingredients

Lidocaine 5%

Purpose

Topical Anesthetic

Uses

For temporary relief of local discomfort, itching, pain, soreness, or burning in the perianal area associated with anorectal disorders.

Warnings

For external use only

Do not use this product

Pregnant or breastfeeding, ask a health professional before use.

When using this product

Do not exceed the recommended daily dosage unless directed by a doctor
Do not put into the rectum by using fingers or any mechanical device or applicator.

Stop use and ask a doctor if

Condition worsens, or does not improve within 7 days. Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase. Discontinue use

Keep out of reach of children

In case of accidental ingestion, seek medical attention immediately

Directions

Adults and Children 12 years and older: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly.
Gently dry by patting or blotting with toilet tissue or a soft cloth, before application of this product. Apply externally to the affected area up to 6 times daily.

Other Information

- Keep away from direct sunlight or heat
- Store in room temperature (59-86°F/15-30°C)

Inactive Ingredients

Aloe barbadensis leaf juice (Aloe vera), Water, Lecithin (Soybean), Propylene Glycol, Tocopheryl Acetate, Carbomer, Menthol, Triethanolamine

30ml / 1.06 Fl.Oz

Drug Facts		Drug Facts (Continued)	
Active ingredient	Purpose	When using this product	
Lidocaine 5%	Topical Anesthetic	<ul style="list-style-type: none"> Do not exceed the recommended daily dosage unless directed by a doctor Do not put into the rectum by using fingers or any mechanical device or applicator. 	
Uses: For temporary relief of local discomfort, itching, pain, soreness, or burning in the perianal area associated with anorectal disorders.		Stop use and ask a doctor if	
Warnings (For external use only)		Condition worsens, or does not improve within 7 days. Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use	
Do not this product			
<ul style="list-style-type: none"> Pregnant or breastfeeding, ask a health professional before use. 			

Drug Facts (Continued)	Drug Facts (Continued)
Keep out of reach of children	<ul style="list-style-type: none"> Children under 12 years of age: consult a doctor.
In case of accidental ingestion, seek medical attention immediately	Other Information
Directions	<ul style="list-style-type: none"> Keep away from direct sunlight or heat Store in room temperature (59-86°F/15-30°C)
<ul style="list-style-type: none"> Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth, before application of this product Apply externally to the affected area up to 6 times daily. 	Inactive Ingredients:
	Aloe barbadensis leaf juice (Aloe vera), Water, Lecithin (Soybean), Propylene Glycol, Tocopheryl Acetate, Carbomer, Menthol, Triethanolamine

Tattoo Numbing Cream

Purpose Lidocaine 5% with Vitamin E

30ml / 1.06 Fl.Oz For external use only

Tapical Pain Treatment for Tattoos




6 hours

Maximum Strength Pain Relief


Correct use steps before tattooing:

- Clean hands and treatment area with mild soap and warm water, rinse thoroughly, then gently pat dry.
- Apply a thick layer onto treatment area. (Make sure the tattoo area and surroundings are white cream)
- Wrap tightly with plastic wrap, wait 45-60 minutes (longer time better effect).
- Wipe away residue, wait another 10 minutes for the numbness to peak.
- Begin procedure.

Notice: Due to the difference of temperature and skin type, the duration of numbness effect will be different. It is recommended to test in a small area first to ensure the best numbness effect. (the longer wrap time, better effect)



Origin: Guangdong Sainite Trading(Shenzhen)Co.,LTD. Floor 3, Jiangnan Building, Yongxiang Road, Bantian street, Longgang District, Shenzhen, Guangdong Province.



6 973787 220968 >

40ml / 1.41 Fl.Oz

Drug Facts		Drug Facts (Continued)	
Active ingredient	Purpose	When using this product	
Lidocaine 5%	Topical Anesthetic	<ul style="list-style-type: none"> Do not exceed the recommended daily dosage unless directed by a doctor Do not put into the rectum by using fingers or any mechanical device or applicator. 	
Uses: For temporary relief of local discomfort, itching, pain, soreness, or burning in the perianal area associated with anorectal disorders.		Stop use and ask a doctor if	
Warnings (For external use only)		Condition worsens, or does not improve within 7 days. Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use	
Do not this product			
<ul style="list-style-type: none"> Pregnant or breastfeeding, ask a health professional before use. 			

Drug Facts (Continued)		Drug Facts (Continued)	
Keep out of reach of children		<ul style="list-style-type: none"> Children under 12 years of age: consult a doctor. 	
In case of accidental ingestion, seek medical attention immediately		Other Information	
Directions		<ul style="list-style-type: none"> Keep away from direct sunlight or heat Store in room temperature (59-86°F/15-30°C) 	
<ul style="list-style-type: none"> Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth, before application of this product Apply externally to the affected area up to 6 times daily. 		Inactive Ingredients:	
		Aloe barbadensis leaf juice (Aloe vera), Water, Lecithin (Soybean), Propylene Glycol, Tocopheryl Acetate, Carbomer, Menthol, Triethanolamine	

Tattoo Numbing Cream

Topical Pain Treatment for Tattoos





Maximum Strength Pain Relief


Purpos Lidocaine 5% with Vitamin E

40ml / 1.41 Fl.Oz For external use only


Correct use steps before tattooing:

- Clean hands and treatment area with mild soap and warm water, rinse thoroughly, then gently pat dry.
- Apply a thick layer onto treatment area. (Make sure the tattoo area and surroundings are white cream)
- Wrap tightly with plastic wrap, wait 45-60 minutes (longer time better effect).
- Wipe away residue, wait another 10 minutes for the numbness to peak.
- Begin procedure.

Notice: Due to the difference of temperature and skin type, the duration of numbness effect will be different. It is recommended to test in a small area first to ensure the best numbness effect. (the longer wrap time, better effect)



Origin: Guangdong
Sainite Trading(Shenzhen)Co.,LTD.
Floor 3, Jiangnan Building,
Yongxiang Road, Bantian street,
Longgang District, Shenzhen,
Guangdong Province.



60ml / 2.12 Fl.Oz

Drug Facts		Drug Facts (Continued)	
Active ingredient Lidocaine 5%.....Topical Anesthetic	Purpose	When using this product	<ul style="list-style-type: none"> Do not exceed the recommended daily dosage unless directed by a doctor Do not put into the rectum by using fingers or any mechanical device or applicator.
Uses: For temporary relief of local discomfort, itching, pain, soreness, or burning in the perianal area associated with anorectal disorders.		Stop use and ask a doctor if	
Warnings (For external use only)		Condition worsens, or does not improve within 7 days. Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase. Discontinue use	
Do not use this product if			
<ul style="list-style-type: none"> Pregnant or breastfeeding, ask a health professional before use. 			

Drug Facts (Continued)		Drug Facts (Continued)	
Keep out of reach of children	In case of accidental ingestion, seek medical attention immediately	<ul style="list-style-type: none"> Children under 12 years of age: consult a doctor. 	
Directions		Other Information	
<ul style="list-style-type: none"> Adults and Children 12 years and older: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth, before application of this product. Apply externally to the affected area up to 6 times daily. 		<ul style="list-style-type: none"> Keep away from direct sunlight or heat Store in room temperature (59-86°F/15-30°C) 	
		Inactive Ingredients:	
		Aloe barbadensis leaf juice (Aloe vera), Water, Lecithin (Soybean), Propylene Glycol, Tocopheryl Acetate, Carbomer, Menthol, Triethanolamine	

Tattoo Numbing Cream

Purpos Lidocaine 5% with Vitamin E

60ml / 2.12 Fl.Oz For external use only

6 hours

Maximum Strength
Pain Relieve

Topical Pain Treatment
for Tattoos

CORRECT USE STEPS BEFORE TATTOOING:

- Clean hands and treatment area with mild soap and warm water (to open pores to help absorb numbing cream), then gently dry.
- Apply a thick layer of about 2mm to the treated area. (Make sure the tattoo area and surroundings are white cream)
- Wrap tightly with plastic wrap, wait 60 minutes (longer time better effect). It is recommended to massage or tap lightly every 10 minutes to help the absorption of the numbing cream
- Wipe away residue, wait another 20-30 minutes for the numbness to peak. And Begin procedure.

Notice: Due to the difference of temperature and skin type, the duration of numbness effect will be different. It is recommended to test in a small area first to ensure the best numbness effect. (the longer wrap time, better effect)

6 973787 220975 >

Origin: Guangdong
Sainite Trading (Shenzhen) Co., LTD.
No.317, 3F, Jiangnan Building,
Yongxiang Road, Bantian Street,
Longgang District, Shenzhen

SAMNYTE TATTOO NUMBING CREAM			
lidocaine emulsion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82929-010
Route of Administration	CUTANEOUS		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MENTHOL (UNII: L7T10EIP3A)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82929-010-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/24/2024	
2	NDC:82929-010-02	40 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/24/2024	
3	NDC:82929-010-03	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/24/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	01/24/2024	

Labeler - Sainite Trading Shenzhen Co., Ltd. (418973870)

Establishment

Name	Address	ID/FEI	Business Operations
Sainite Trading Shenzhen Co., Ltd.		418973870	label(82929-010) , manufacture(82929-010)

Revised: 1/2024

Sainite Trading Shenzhen Co., Ltd.