

SIGNATURE CARE LIDOCAINE CREAM- lidocaine cream
Better Living Brands 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.

Pain Relief Cream

Drug Facts

Active ingredient

Lidocaine HCL 4%

Purpose

Topical anesthetic

Uses

- Temporarily relieves minor pain

Warnings

For external use only

Do not use

- on large areas of the body or on cut, irritated or swollen skin
- on puncture wounds
- for more than one week without consulting a doctor

When using this product

use only as directed. read and follow all directions and warnings on this carton.

do not allow contact with the eyes

do not bandage or apply local heat (such as heating pads) to the area of use.

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days.
- **If pregnant or breast feeding**, ask a health professional before use.

Keep this and all drugs out of the reach of children and pets.

If swallowed, get medical help or contact Poison Control Center right away.

Directions

- **Adults and children over 12 years:**
- apply a thin layer of affected area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period
- **Children under 12 years or younger:** ask a doctor

Other information

- Store at controlled room temperature 20°-25°C (68°-77°F)

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, C30-45 Alkyl Cetearyl Dimethicone Crosspolymer, Caprylyl Methicone, Cetearyl Alcohol, Ceteth-20 Phosphate, Dicyetyl Phosphate, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Glyceryl Stearate, Phenoxyethanol, SD Alcohol 40, Steareth-21, Water (purified)

Questions? 1-888-723-3929**Principal Panel-Bottle**

Signature Care NDC 21130-544-27

Maximum Strength

4% Lidocaine

Pain Relieving Cream

NET WT. 2.7 oz (76g)

NDC 21130-544-27



Quality Guaranteed

**MAXIMUM STRENGTH LIDOCAINE
WITHOUT A PRESCRIPTION***

LIDOCAINE PAIN RELIEF CREAM

LIDOCAINE HCl 4% EXTERNAL ANALGESIC

- Maximum Strength Lidocaine
Without a Prescription*

*Among OTC Topical Analgesics

NET WT 2.7 OZ (76 g)



WITH ALOE

Active ingredient **Purpose**

Lidocaine HCl 4%.....Topical Anesthetic
Uses temporarily relieves minor pain.

Warnings For external use only.

Do not use • on large areas of the body or on cut, irritated or swollen skin • on puncture wounds • for more than one week without consulting a doctor

When using this product • use only as directed. Read and follow all directions and warnings on carton • do not allow contact with the eyes • do not bandage or apply local heat (such as heating pads) to the area of use

DISTRIBUTED BY:

BETTER LIVING BRANDS LLC
P.O. BOX 99
PLEASANTON, CA 94566-0009
1-888-723-3929

RD 20157
S5408

PEEL HERE FOR FULL DRUG INFO

Stop use and ask a doctor if • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breast-feeding ask a health professional before use.

Keep out of reach of children and pets.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children over 12 years:

• apply a thin layer to affected area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period

children 12 years or younger: ask a doctor.

Other information

• Store at controlled room temperature 68°-77°F (20°- 25°C).

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, C30-45 Alkyl Cetearyl Dimethicone Crosspolymer, Caprylyl Methicone, Cetearyl Alcohol, Ceteth-20 Phosphate, Dicyetyl Phosphate, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Glyceryl Stearate, Phenoxyethanol, SD Alcohol 40, Steareth-21, Water (purified)

Save carton for complete drug facts

Principal Panel - Carton

Signature Care NDC 21130-544-27

Maxium Strength

4% Lidocaine

Pain Relieving Cream

NET WT. 2.7 oz (76 g)



SIGNATURE CARE LIDOCAINE CREAM

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-544
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SILICON (UNII: Z4152N8IUI)	
ALCOHOL (UNII: 3K9958V90M)	
CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 132584PQMO)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STEARETH-21 (UNII: 53J3F32P58)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETEARETH-2 PHOSPHATE (UNII: 8NSU66JGZR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-544-27	1 in 1 CARTON	08/03/2020	
1		76 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/03/2020	

Labeler - Better Living Brands LLC (009137209)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(21130-544)