

SHEFFIELD LIDOCAINE- lidocaine cream
Sheffield Pharmaceuticals LLC

Sheffield Pharmaceutical Lidocaine Cream

Drug Facts

Active ingredient

Lidocaine 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

Benzyl Alcohol, Carbomer, Cholesterol, Hydrogenated Lecithin, Polysorbate 80, Propylene Glycol, Tocopheryl Acetate, Trolamine, Water (purified)

Questions?(

Principal Panel-Tube

Sheffield NDC 11527-191-30

4% Lidocaine

Topical Anesthetic Cream

NET WT. 30g (1.06 oz)





Principal Panel - Carton

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NET WT. 30g (1.06 oz)



SHEFFIELD LIDOCAINE

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11527-191	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)		LIDOCAINE	40 mg in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
BENZYL ALCOHOL (UNII: LKG8494WBH)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
CHOLESTEROL (UNII: 97C5T2UQ7J)				
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
TROLAMINE (UNII: 9O3K93S3TK)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11527-191-30	1 in 1 CARTON	12/22/2020	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	12/22/2020		

Labeler - Sheffield Pharmaceuticals LLC (151177797)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(11527-191)