

LIDOCAINE- lidocaine cream
Advanced Rx Pharmacy of Tennessee, 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.

Lidocaine Cream 4%

Drug Facts

Active Ingredient

Lidocaine 4% w/w

Purpose

Topical anesthetic

Uses

temporarily relieves pain and itching due to

- minor cuts
- minor scrapes
- minor burns
- sunburn
- minor skin irritation
- insect bites

Directions

- Adult and children 2 years and older: Apply externally to the affected area up to 3 to 4 times a day.
- Children under 2 years of age: Consult a doctor.

Warnings

For external use only.

Do not use

- in or near the eyes
- in large quantities, particularly over raw or blistered areas

Stop use and ask a doctor if

- **allergic reaction occurs**
- **condition worsens or does not improve within 7 days**
- **symptoms clear up and return within a few days**
- **redness, irritation, swelling, pain or other symptoms begin or increase**

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Other Information

- May be applied under occlusive dressing.
- Store at room temperature, 20–25°C (68–77°F) Excursions permitted 15–30°C (59–86°F) [see USP Controlled Room Temperature].

Inactive ingredients

Benzyl Alcohol, Carbopol 940, Hydrogenated Lecithin, Polysorbate 80, Propylene Glycol, Purified Water, Trolamine and Vitamin E Acetate.

Questions?

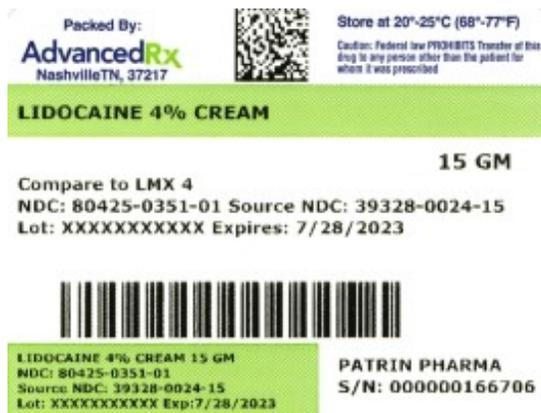
Call 800-936-3088

How Supplied/Storage and Handling

Lidocaine 4% Cream is supplied in:

15g tube NDC: 80425-0351-01

Store at room temperature, 20–25°C (68–77°F) Excursions permitted 15–30°C (59–86°F) [see USP Controlled Room Temperature].



LIDOCAINE

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80425-0351(NDC:39328-024)
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 HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)				
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
TROLAMINE (UNII: 9O3K93S3TK)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0351-1	1 in 1 CARTON	07/31/2023	
1		15 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 final	part348	07/31/2023		

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0351)