

LIDOCAINE 4% TOPICAL ANESTHETIC CREAM- lidocaine 4% cream
Oncor Pharmaceuticals

Lidocaine 4% Cream

Drug Facts

Active Ingredients

Lidocaine 4% w/w

Purpose

Topical Anesthetic

Uses

Temporarily relieves pain and itching due to:

- Minor cuts
- Minor scrapes
- Sunburn
- Minor burns
- Minor skin irritations
- Insect bites

Warnings

For external use only.

When using this product

- Do not use in or near the eyes.
- Do not use in large quantities, particularly over raw surfaces 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.

You may report side effects by calling Oncor Pharmaceuticals (9 a.m. to 5 p.m. EST), at 1-443-876-7900 or FDA at 1-800-FDA-1088.

Directions

- Adults and children 2 years and older: apply externally to the affected area up to 3-4 times daily.
- Children under 2 years of age: consult a physician.

Inactive Ingredients

Cetyl alcohol, Citric acid, Glycerin, Glyceryl stearate SE, Mineral oil, PEG-100 stearate, Phenoxyethanol, Purified water, Stearyl alcohol, White petrolatum, Xanthan gum.

See crimp of tube or carton for lot and exp. date.

RETAIN CARTON FOR COMPLETE DRUG FACTS.

Other information

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

Manufactured In USA For :

ONCOR PHARMACEUTICALS
8815 Center Park Dr Suite 430
Columbia
Maryland 21045

Package Label

ONCOR PHARMACEUTICALS

NDC 83720- 523-01

Lidocaine 4% Cream

Topical Anesthetic Cream

For External Use Only

Not For Ophthalmic Use

This product contains child-resistant packaging. To open, push down on the cap of the tube while turning and lift off.

NET WT. 1.05 OZ. (30 gm)

Lidocaine
4% Cream
Topical Anesthetic Cream



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Rev. 05/24

Lidocaine
4% Cream
Topical Anesthetic Cream

LIDOCAINE 4% TOPICAL ANESTHETIC CREAM

lidocaine 4% cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:83720-523 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 4 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| CITRIC ACID ACETATE (UNII: DSO12WL7AU) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| WATER (UNII: 059QF0KOOR) | |
| WHITE PETROLATUM (UNII: B6E5W8RQJ4) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCERYL STEARATE SE (UNII: FCZ5MH785I) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:83720-523-01 | 1 in 1 CARTON | 05/22/2024 | |
| 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 | 05/22/2024 | |

Labeler - Oncor Pharmaceuticals (119032580)

Registrant - Oncor Pharmaceuticals (119032580)

