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

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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.

#### Lidocaine 4% Cream

#### **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 Rev. 05/24

## 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)

Topical Anesthetic Cream

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NDC 83720- **523**-01

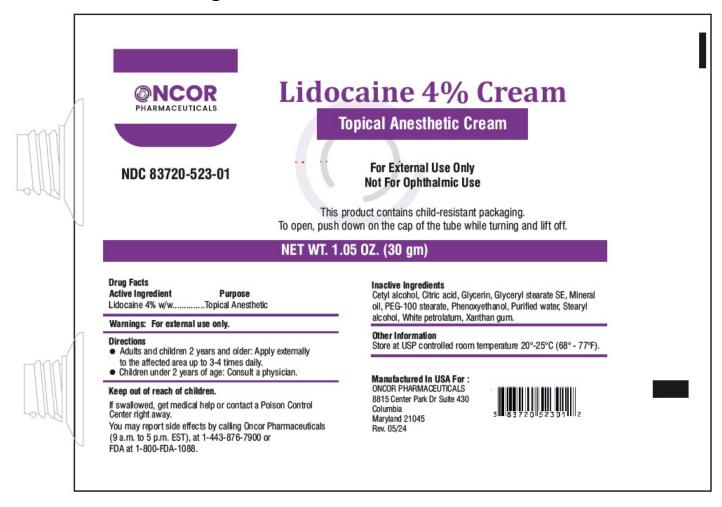
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## **LIDOCAINE 4% TOPICAL ANESTHETIC CREAM**

lidocaine 4% cream

**Active Ingredient/Active Moiety** 

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

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: 059QF0KO0R)		
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	05/10/2024		
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	05/10/2024		

## Labeler - Oncor Pharmaceuticals (119032580)

## Registrant - Oncor Pharmaceuticals (119032580)

Revised: 5/2024 Oncor Pharmaceuticals