

## **4 LIDOCAINE TOPICAL ANESTHETIC- lidocaine cream RUGBY LABORATORIES**

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**4% Lidocaine Topical Anesthetic Cream**

### ***Drug Facts***

#### ***Active ingredient***

Active ingredient

#### ***Purpose***

Topical Analgesic

### **Uses**

temporarily relieves pain and itching due to:

- minor cuts
- minor scrapes
- sunburn
- minor skin irritations
- minor burns
- 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

Do not apply over large areas of the body.

#### **Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

***Directions***

- Adults and children 2 years and older: Apply externally to the affected area up to 3-4 times daily.
- Children under 2 years: Consult a doctor.

***Other information***

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

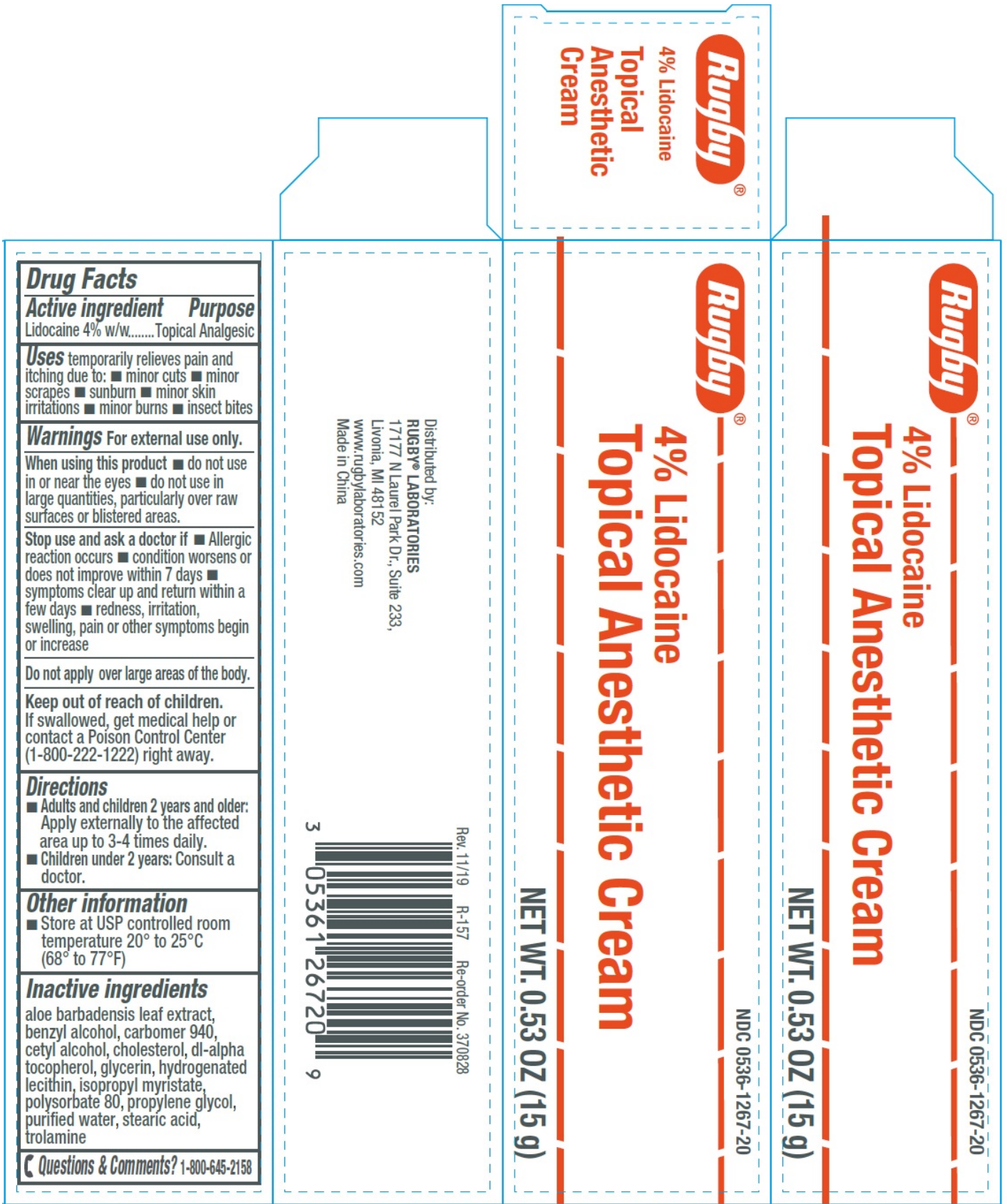
***Inactive ingredients***

aloe barbadensis leaf extract, benzyl alcohol, carbomer 940, cetyl alcohol, cholesterol, di-alpha tocopherol, glycerin, hydrogenated lecithin, isopropyl myristate, polysorbate 80, propylene glycol, purified water, stearic acid, trolamine

***Questions & Comments?***

1-800-645-2158

**Package Labeling:**



**Drug Facts**

**Active ingredient Purpose**  
Lidocaine 4% w/w.....Topical Analgesic

**Uses** temporarily relieves pain and itching due to: ■ minor cuts ■ minor scrapes ■ sunburn ■ minor skin irritations ■ minor burns ■ 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

Do not apply over large areas of the body.

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**Questions & Comments?** 1-800-645-2158

**4 LIDOCAINE TOPICAL ANESTHETIC**

lidocaine cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-1267
<b>Route of Administration</b>	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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1267-20	15 g in 1 BOX; Type 0: Not a Combination Product	04/30/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	04/30/2020	

**Labeler** - RUGBY LABORATORIES (079246066)