

4 LIDOCAINE TOPICAL ANESTHETIC- lidocaine cream RUGBY LABORATORIES

4% Lidocaine Topical Anesthetic Cream

Drug Facts

Active ingredient

Lidocaine 4% W/W

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 use

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)

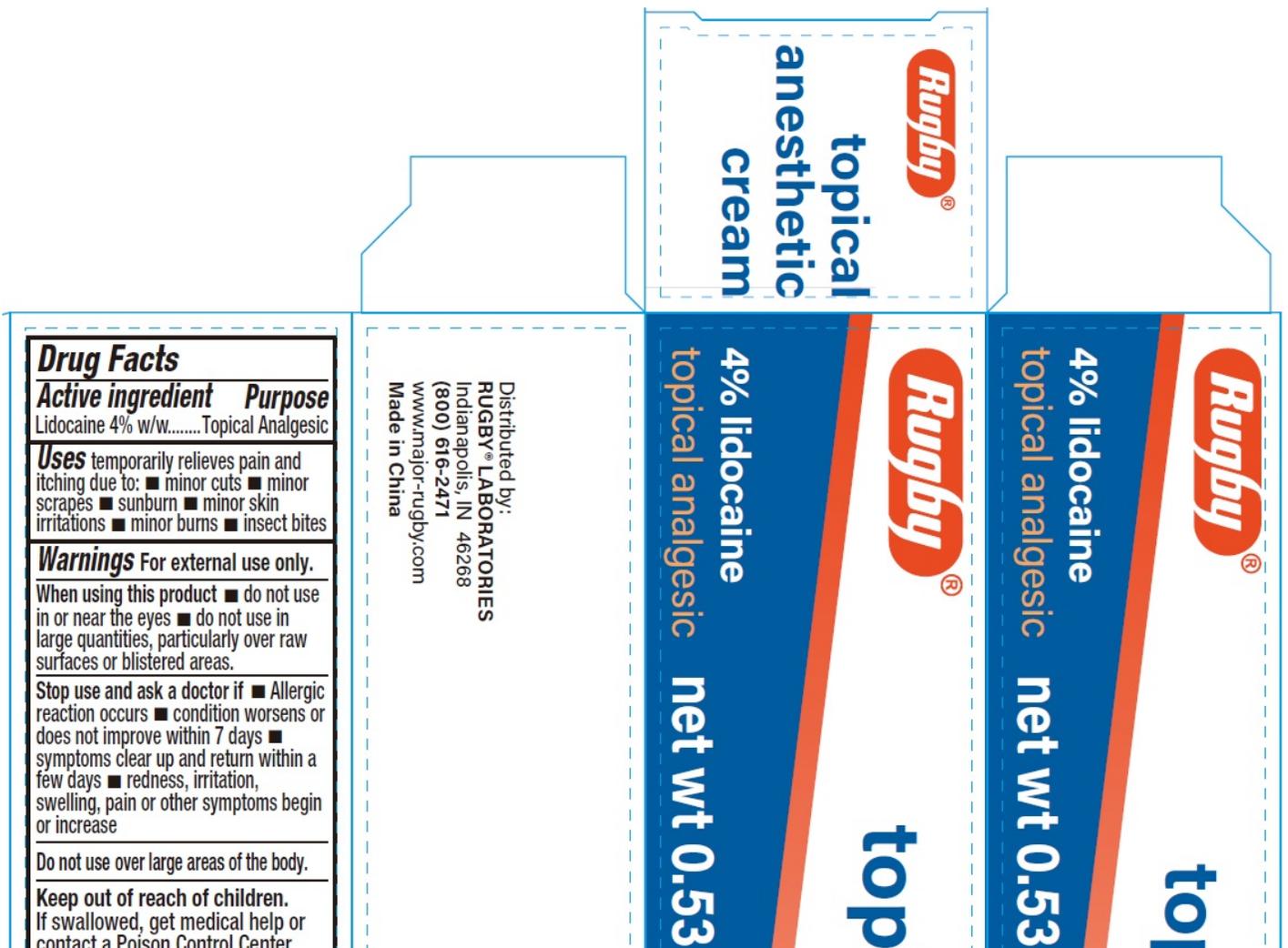
Inactive ingredient

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

Questions or comments?

1-800-639-3803

Package Labeling:



(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 homopolymer, cetyl alcohol, cholesterol, dl-alpha-tocopherol, glycerin, hydrogenated lecithin, isopropyl myristate, polysorbate 80, propylene glycol, purified water, sodium hydroxide, stearic acid

Questions or comments? 1-800-639-3803



Rev 03/25 R-157 Re-order No. 370828

oz (15 g)

ical anesthetic
cream

NDC 0536-1267-20

oz (15 g)

ical anesthetic
cream

NDC 0536-1267-20

3.3mm net wt 0.53 oz (15 g)



NDC 0536-1267-20

topical anesthetic cream

4% lidocaine
topical analgesic net wt 0.53 oz (15 g)

TAMPER-EVIDENT: Do not use if foil seal is broken or missing

Active ingredient Lidocaine 4% w/w **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 use** 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 of age: 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 homopolymer, cetyl alcohol, cholesterol, dl-alpha-tocopherol, glycerin, hydrogenated lecithin, isopropyl myristate, polysorbate 80, propylene glycol, purified water, sodium hydroxide, stearic acid

Questions or comments?
1-800-639-3803

Distributed by: RUGBY® LABORATORIES
Indianapolis, IN 46268
(800) 616-2471
www.major-rugby.com
Made in China

Rev. 03/25 R-157 Re-order No. 370828



4 LIDOCAINE TOPICAL ANESTHETIC

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1267
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
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)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

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)

Registrant - Zhejiang Jingwei Pharmaceutical Co., Ltd. (530876549)

Revised: 6/2025

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