JELCAINE STERILE- lidocaine hcl jelly usp, 2% jelly
Brookfield Pharmaceuticals, LLC

Jelcaine Sterile

Active Ingredients

Lidocaine HCl 2% w/v

Purpose

Topical anesthetic

Uses

For temporary relief of pain and itching due to:

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

Warnings

For external use only.

When using this product

- Avoid contact with 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 if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor
- you experience any redness, irritation, swelling, pain or other symptoms begin or increase

Keep out of reach of children

PACKAGE NOT CHILD RESISTANT. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 2 years of age and older: Apply externally to the affected area not more than 3-4 time daily.
- Children under 2 years of age: Do not use. Consult a doctor.

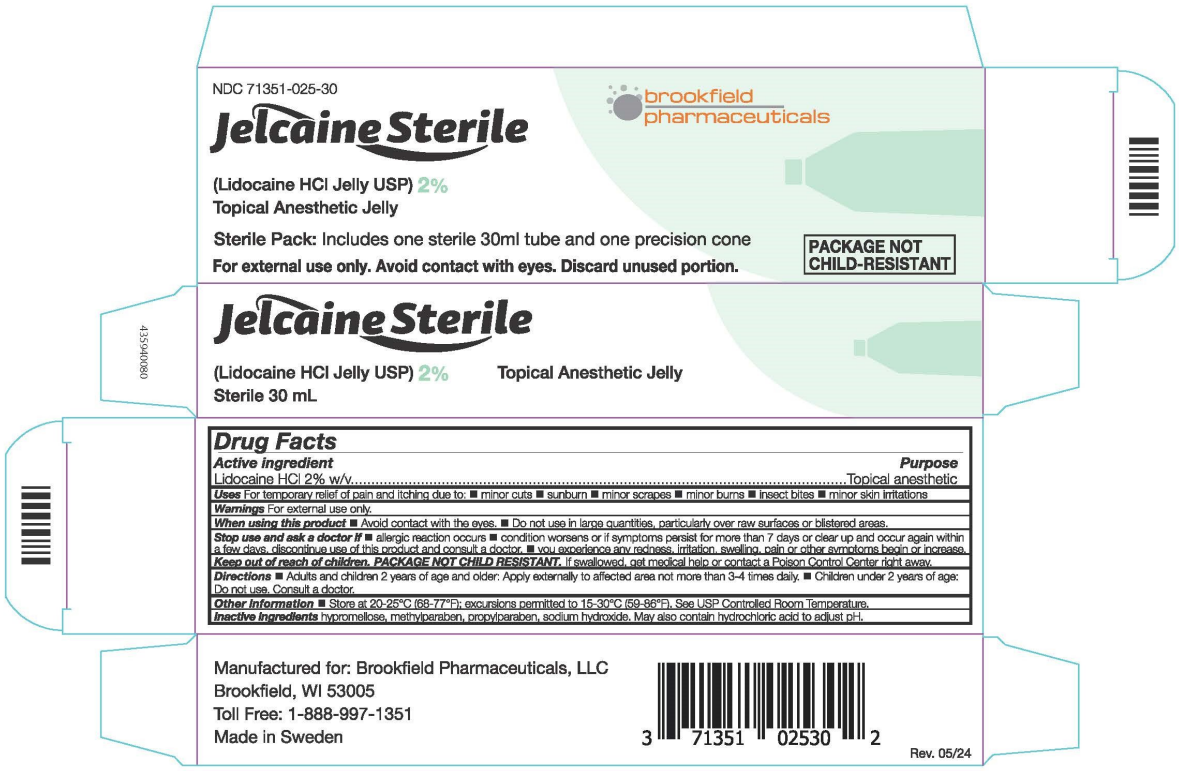
Other information

- Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). See USP Controlled Room Temperature.

Inactive ingredients

hypromellose, methylparaben, propylparaben, sodium hydroxide. May also contain hydrochloric acid to adjust pH.

Jelcaine Sterile (Lidocaine HCl Jelly USP) 2%



JELCAINE STERILE

lidocaine hcl jelly usp, 2% jelly

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71351-025

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROCHLORIC ACID (UNII: QTT17582CB)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71351-025-30	30 mL in 1 TUBE; Type 0: Not a Combination Product	09/10/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	09/10/2024	

Labeler - Brookfield Pharmaceuticals, LLC (080592685)

Revised: 8/2024 Brookfield Pharmaceuticals, LLC