

1ST RELIEF TOPICAL- lidocaine and menthol spray
1st Class Pharmaceuticals, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

1st Relief Topical

ACTIVE INGREDIENT:

Lidocaine 4.00%

Menthol 1.00%

Topical Analgesic

Topical Analgesic

Indications:

For temporary relief of pain associated with minor burns, minor cuts, scrapes, insect bites or skin irritations.

Warnings:

- For external use only
- Avoid contact with eyes
- Do not apply to open wounds or damages skin.

- If symptoms persist for more than seven days, discontinue use and consult physician.

Keep out of reach of children.

If swallowed, consult physician.

Directions

- Apply directly to affected area. Do not use more than four times per day. Children under two-years of age: consult a physician.

Other Ingredients:

Aqua (Deionized Water), ARNICA MONTANA, BOSWELLIA SERRATA, CETYL MYRISTOLEATE, EMU OIL, GLYCYRRHIZA GLABRA, METHYLSULFONYLMETHANE (MSM), POLYSORBATE 20, POTASSIUM SORBATE, SD-Alcohol 40B, SODIUM BENZOATE

If pregnant or breast feeding, contact physician prior to use.

Package Label

NDC 69094-226-04

1st Class

PHARMACEUTICALS INC.

1st RELIEF

TOPICAL SPRAY

For temporary relief of:

- backache • bruises • arthritis • sprains

4 Fl OZ. (118 ml)

Distributed by:

1st Class PHARMACEUTICALS INC.

Los Angeles, CA 90064

www.1stclasspharmaceuticals.com

NDC 69094-226-04

DRUG FACTS

Active Ingredient:
Lidocaine 4.00% . . . Topical Analgesic
Menthol 1.00% . . . Topical Analgesic

Indications:
For temporary relief of pain associated with minor burns, minor cuts, scrapes, insect bites or skin irritations.

Warnings:

- For external use only.
- Avoid contact with eyes.
- Do not apply to open wounds or damaged skin.
- If symptoms persist for more than seven days, discontinue use and consult physician.
- Keep out of reach of children.
- If swallowed, consult physician.
- Do not bandage tightly.
- If pregnant or breast feeding, contact physician prior to use.


1st RELIEF
TOPICAL SPRAY

DRUG FACTS (continued)

Directions:
Apply directly to affected area. Do not use more than four times per day. Children under two-years of age; consult a physician.

Other Ingredients:
Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata, Cetyl Myristoleate, Emu Oil, Glycyrrhiza Glabra (Licorice) Extract, Methylsulfoniummethane (MSM), Polysorbate-20, Potassium Sorbate, SD-Alcohol 40B, Sodium Benzoate.

For temporary relief of:

- backache • bruises
- arthritis • sprains

4 Fl OZ. (118 ml)

Distributed by:
1st Class Pharmaceuticals Inc.
Los Angeles, CA 90064
www.1stclasspharmaceuticals.com

1ST RELIEF TOPICAL

lidocaine and menthol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69094-226
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 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
BOSWELLIA SERRATA WHOLE (UNII: X7B7P649WQ)	
CETYL MYRISTOLEATE (UNII: 87P8K33Q5X)	
EMU OIL (UNII: 344821WD61)	
GLYCYRRHIZA GLABRA LEAF (UNII: GH32M797Y9)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69094-226-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/02/2014	

Labeler - 1st Class Pharmaceuticals, Inc. (079448685)

Revised: 12/2017

1st Class Pharmaceuticals, Inc.