

CUTIECAINE - topical lidocaine (4% w/w) cream
Innovatech 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.

Drug Facts

Benzocaine 18% (w/w), Tetracaine 2% (w/w), Inactive Ingredients; water, Isoprpopyl Alcohol, glycerin, Ethyl alcohol, Staeric Acid, Carbomer, Sodium Hyaluronate, castor oil, Innovatech Inc, Net Wt. 15g

Use for reducing pain or discomfort from minor cuts, abrasions, minor burns, sun burns, insect bites, poison ivy, hemorrhoids pain and Itching. Use small amount (1 to 2 gm) of this medication, apply on the skin with gentle massage to numb the skin or relieve pain (do not occlude). Children under 2 years of age, consult your doctor

- Do not use in or near the eyes
- Do not use in large amount particularly over the raw surfaces or blisters

Stop use and Ask Doctors if

- Allergic reactions occurs
- Condition worsen and does not improve
- Symptoms clean up and returns within few day
- itching, redness, burning , swelling or other symptoms occurs
- Keep both used and unused medicine out of the reach of children or pets
- If swallowed get medical attention right away Call your doctor immediately.

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Inactive Ingredients; water, Isoprpopyl Alcohol, glycerin, Ethyl alcohol, Staeric Acid, Carbomer, Sodium Hyaluronate, castor oil, sodium lauryl sulfate,

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carton.jpg

DIN; 02344971

Carton.jpg

NDC 50876-182-01

Dermacaine-R

Rapid Acting
Topical Anesthetic Cream

Benzocaine 18% w/w
Tetracaine 2% w/w

Innovatech Inc
2002-B Hazel Street
Birmingham, MI 48009
Tel; (248)-341-3401

Net Weight; 15g

Net Wt. 15 g

Label; Drug Facts

Active Ingredient Benzocaine 18% w/w
Tetracaine 2% w/w

Topical Anesthetic

Uses; to reduce pain or discomfort from;

- minor cuts,
- scratches
- sunburn,
- insect bites,
- cold sores
- hemorrhoids Pain and Itching
- Minor burns
- minor cosmetic procedures
- minor dental procedures.

Warnings; For external uses only

When using this product;

Do not use in or near the eyes
Do not in large amount particularly over the raw surfaces or blisters
Stop use and Ask Doctors if
Allergic reactions occurs
Condition worsen and does not improve
Symptoms clean up and returns within few day
itching, redness, burning, swelling or other symptoms occurs
Keep both used and unused medicine out of the reach of children or pets

Directions; Use small amount (1 to 2 gm) of this medication, apply on the skin with gentle massage to numb the skin or relieve pain. Children under 2 years of age, consult your doctor

Storage; store at room temperature (25°C) and away from heat.

Inactive Ingredients; water, Isopropyl Alcohol, glycerin, Ethyl alcohol, Stearic Acid, Carbomer, Sodium Hyaluronate, castor oil, mnthol, peppermint

Net Weight: 15 g

CUTIECAINE

topical lidocaine (4% w/w) cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50876-182 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| BENZOCAINE (UNII: U3RS Y48JW5) (BENZOCAINE - UNII:U3RS Y48JW5) | BENZOCAINE | 180 mg in 1 g |

| | | | | |
|--|---|-----------------------------|-----------------------------|---------------------------|
| TETRACAINE (UNII: 0619F35CGV) (TETRACAINE - UNII:0619F35CGV) | | TETRACAINE | 20 mg in 1 g | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| WATER (UNII: 059QF0K00R) | | | | |
| CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | | | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | | | | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | | | | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | | | | |
| ALCOHOL (UNII: 3K9958V90M) | | | | |
| ALOE (UNII: V5VD430YW9) | | | | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | | | | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | | | | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | | | | |
| CASTOR OIL (UNII: D5340Y2I9G) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:50876-182-02 | 1 in 1 BOX | | |
| 1 | NDC:50876-182-01 | 15 g in 1 TUBE | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part348 | 08/31/2010 | | |

Labeler - Innovatech Inc (833205961)

Registrant - Innovatech Inc (833205961)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------|---------|-----------|------------------------------------|
| Innovatech Inc | | 833205961 | manufacture, label, analysis, pack |