

TETRACAINE- tetracaine gel
Bellus Medical, LLC

2% Tetracaine Gel

Tetracaine HCL 2%

Water, Glycerin, Propylene Glycol, Hydroxyethyl Cellulose, Phenoxyethanol, Caprylyl Glycol, Aloe Barbadensis (Aloe Vera) Leaf Extract, Sorbic Acid, Tetrasodium EDTA

Uses : For the temporary relief of discomfort and pain associated with

- Minor burns and skin irritations
- Minor cuts and scrapes
- Itching

Directions : Adults and Children 12 years of age and older Apply to affected area not more than 3-4 times daily.

Warnings : For external use only. Avoid contact with the eyes.

DO NOT USE : In large quantities, particularly over raw surfaces and blistered areas.

Stop use and ask a doctor if:

- Skin becomes irritated
- Condition worsens or symptoms last more than 7 days
- Symptoms clear up and reoccur within a few days.



Topical Anesthetic

Keep out of reach of children.

Uses : For the temporary relief of discomfort and pain associated with

- Minor burns and skin irritations
- Minor cuts and scrapes
- Itching

Directions : Adults and Children 12 years of age and older Apply to affected area not more than 3-4 times daily.

<p>DRUG FACTS Active Ingredients: Tetracaine HCl 2%.....Purpose: Topical Anesthetic</p> <p>USES: For the temporary relief of discomfort and pain associated with minor burns and skin irritations - minor cuts and scrapes - itching.</p> <p>DIRECTIONS: Adults and children 12 years of age and older apply to affected area not more than 3-4 times daily.</p> <p>WARNINGS: For external use only. Avoid contact with the eyes.</p> <p>DO NOT USE: In large quantities, particularly over raw surfaces or blistered areas.</p> <p>Stop use and ask a doctor if: skin becomes irritated - condition worsens or symptoms last more than 7 days - symptoms clear up and reoccur within a few days.</p> <p>INACTIVE INGREDIENTS: Water, Glycerin, Propylene Glycol, Hydroxyethyl Cellulose, Phenoxyethanol, Caprylyl Glycol, Aloe Barbadensis (Aloe Vera) Leaf Extract, Sorbic Acid, Tetrasodium EDTA</p> <p>Other information: Questions or Comments? Call 888-272-2869 or visit bellusmedical.com. Distributed exclusively by Bellus Medical LLC, Addison, Texas 75001 USA</p> <p>PNUMBT REV. B</p>	<p>DRUG FACTS Active Ingredients: Tetracaine HCl 2%.....Purpose: Topical Anesthetic</p> <p>USES: For the temporary relief of discomfort and pain associated with minor burns and skin irritations - minor cuts and scrapes - itching.</p> <p>DIRECTIONS: Adults and children 12 years of age and older apply to affected area not more than 3-4 times daily.</p> <p>WARNINGS: For external use only. Avoid contact with the eyes.</p> <p>DO NOT USE: In large quantities, particularly over raw surfaces or blistered areas.</p> <p>Stop use and ask a doctor if: skin becomes irritated - condition worsens or symptoms last more than 7 days - symptoms clear up and reoccur within a few days.</p> <p>INACTIVE INGREDIENTS: Water, Glycerin, Propylene Glycol, Hydroxyethyl Cellulose, Phenoxyethanol, Caprylyl Glycol, Aloe Barbadensis (Aloe Vera) Leaf Extract, Sorbic Acid, Tetrasodium EDTA</p> <p>Other information: Questions or Comments? Call 888-272-2869 or visit bellusmedical.com. Distributed exclusively by Bellus Medical LLC, Addison, Texas 75001 USA</p> <p>PNUMBT REV. B</p>	<p>BELLUS MEDICAL</p>  <p>2% TETRACAINE</p> <p>.14FL OZ/4ML</p>	<p>BELLUS MEDICAL</p>  <p>2% TETRACAINE</p> <p>.14FL OZ/4ML</p>
---	---	--	--

TETRACAINE

tetracaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71888-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRACAINE HYDROCHLORIDE (UNII: 5NF5D4OPCI) (TETRACAINE - UNII:0619F35CGV)	TETRACAINE HYDROCHLORIDE	20 mg in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE SODIUM (UNII: MP1J8420LU)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PHENOXYETHANOL (UNII: HIE492Z Z 3T)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z 83H0X)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:71888-103			

1	NDC: 71888-103-02	12 in 1 BOX	06/01/2017	
1	NDC: 71888-103-01	4 mL in 1 PACKET; Type 0: Not a Combination Product		
Marketing Information				
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	OTC Monograph Drug	M017	06/01/2017	

Labeler - Bellus Medical, LLC (005677967)

Registrant - Bellus Medical, LLC (005677967)

Revised: 5/2023

Bellus Medical, LLC