

**NUMFAST TETRACAINE GREEN- tetracaine cream
Unit Dose, Ltd.**

Numfast Tetracaine Green

Drug Facts

Active Ingredient

Tetracaine 2% w/w

Purpose

Local Anesthetic

Uses:

Temporarily relieves pain from minor scrapes

WARNINGS

For External Use only

When using this product

- Do not get into the eyes
- Do not use more than directed
- Do not swallow

Stop use and ask a doctor if

- pain worsens or does not improve within 7 days or cleans up and appears again in a few days
- **you develop an allergy**

Keep out of reach of children

- If swallowed, get medical help right away or contact a Poison Control Center right away.

Directions:

Children under 12 years-ask a doctor

- **Adults: Apply 1-2 gm to desired area and wait 12 to 60 minutes. Remove excess. May repeat 2-3 times/day.**

Questions?

Call toll free 888/452-4946

Inactive Ingredients:

Water (Aqua), Mineral Oil, Petrolatum, Stearyl Alcohol, Propylene Glycol, Cetearyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Ceteareth-20, Disodium EDTA, Carbomer, Triethanolamine, Propylparaben, Methylparaben, Diazolidinyl Urea, Blue 1, Yellow 10, BHT

Package Labeling:



Drug Facts	Topical Anesthetic Creme	Unit Dose Ltd	<p>•Do not use more than directed • Do not swallow Stop use and ask a doctor if _____ •pain worsens or does not improve within 7 days or clears up and appears again in a few days •<i>you develop an allergy</i> Keep out of reach of children •If swallowed, get medical help right away or contact a Poison Control Center right away.</p>	<p>Directions: Children under 12 years-ask a doctor Net wt. 15 gms. •Adults: Apply 1-2gm to desired area and wait 12 to 60 minutes. Remove excess. May repeat 2-3 times/day. Questions? Call toll free 888/452-4946 Inactive Ingredients: Water (Aqua), Mineral Oil, Petrolatum, Stearyl Alcohol, Propylene Glycol, Cetearyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Ceteareth-20, Disodium EDTA, Carbomer Triethanolamine, Propylparaben, Methylparaben, Diazolidinyl Urea, Blue 1, Yellow 10, BHT</p>
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NUMFAST TETRACAINE GREEN
 tetracaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67194-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRACAINE (UNII: 0619F35CGV) (TETRACAINE - UNII:0619F35CGV)	TETRACAINE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67194-020-01	15 g in 1 JAR; Type 0: Not a Combination Product	01/20/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	01/20/2016	

Labeler - Unit Dose, Ltd. (119080393)