TETRI-AG- tetracaine ointment
Singular Dreamer, Ltd dba True Marker

Active Ingredient Purpose

Tetracaine 1.9%. Topical Analgesic

Use

For the temporary relief of: Pain, associated with

- Minor burns
- Minor cuts
- Scrapes
- Sunburn

Warnings

For external use only.

Do not use

- in large quantities
- over raw surfaces
- blistered areas
- on wounds or damaged skin
- with a heating pad
- if you are allergic to any ingredients of this product

When using this product

- use only as directed
- avoid contact with the eyes, mucous membranes or rashes
- do not bandage tightly

Stop use and ask a doctor if:

- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- skin reactions occur, such as rash, itching, redness, irritation, pain, swelling, and blistering
- conditions worsen

If pregnant or breast feeding, ask health professional before use.

Keep out of reach of children and pets. If swallowed, get medical help or contact a Poison Control Center (-1800-222-1222) right away.

Directions:

Adults and children 2 years of age and older:

- Apply to affected area not more than 3 to 4 times daily.

Children under 2 years of age:
- do not use, consult a doctor.

Other Information:

Store at 20-25 C (68-77F). [see USP Controlled Room Temperature].

Inactive Ingredients:

Aqua (Deionized Water), Methylisothiazolinone, PEG-8, PEG-8 Stearate, PEG-100 Stearate, Polyethylene Glycol

Questions or comments?

Call 1-888-811-2634

Product label

TETRI-AG
tetracaine ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83035-7120
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRACAINE (UNII: 0619F35CGV) (TETRACAINE - UNII:0619F35CGV)	TETRACAINE	1.9 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PEG-8 STEARATE (UNII: 2P9L47VI5E)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83035-7120-3	1 in 1 BOTTLE	01/24/2024	
1		30 g in 1 TUBE; 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	01/24/2024	

Labeler - Singular Dreamer, Ltd dba True Marker (129504103)

Registrant - Singular Dreamer, Ltd dba True Marker (129504103)

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