TECNU CALAGEL- diphenhydramine hydrochloride gel Tec Laboratories Inc.

Diphenhydramine HCL 2%

Purpose Topical analgesic / antihistamine

for temporary relief of pain and itching associated with:

- minor burnssunburnminor cutsscrapesinsect bites
- minor skin irritations

rashes due to: •poison oak •poison ivy •poison sumac

DO NOT USE:

- •if allergic to sulfites •on children under 2 years of age unless directed by a doctor
- •with any other products containing diphenydramine, even one taken by mouth
- •on deep puncture wounds, animal bites or serious burns unless directed by a doctor
- •on large areas of the body
- •on chicken pox •on measles

When using this product:

- •KEEP OUT OF REACH OF CHILDREN
- •if swallowed, get medical help or contact a poison control center right away
- avoid contact with eyes

Stop use and ask a doctor if: •condition worsens

•symptoms persist for more than 7 days or clear up and occur again within a few days

Directions •do not use more often than directed

- •adults and children 2 years of age and older
- •cleanse skin with soap and warm water and dry affected area
- •apply to affected area not more than 3 times daily
- •may be covered with a sterile bandage, if bandaged, let dry first
- •children under 2 years of age do not use, consult a doctor

Other Information Store at 59 to 86°F (15 to 30°C)

benzethonium chloride, disodium EDTA, fragrance, hypromellose,

menthol, polysorbate 20, purified water, sodium metabisulfite, zinc acetate

Questions? Call 1-800-482-4464

serious side effects may be reported to this number.

double hit of white behind drug facts box







TECNU CALAGEL

diphenhydramine hydrochloride gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51879-802

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40)	DIPHENHYDRAMINE	20 mg
(DIPHENHYDRAMINE - UNII:8GTS82S83M)	HYDROCHLORIDE	in 1 g

Inactive Ingredients	
Ingredient Name	Strength
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ZINC ACETATE (UNII: FM5526K07A)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	

WATER (UNII: 059QF0KO0R)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51879-802- 06	1 in 1 CARTON	06/20/2019	
1	NDC:51879-802- 66	178.9 g in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51879-802- 66	178.9 g in 1 BOTTLE; Type 0: Not a Combination Product	06/20/2019	
3	NDC:51879-802- 44	144 in 1 CARTON	07/23/2019	
3	NDC:51879-802- 16	1.86 g 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	06/20/2019	

Labeler - Tec Laboratories Inc. (083647792)

Establishment				
Name	Address	ID/FEI	Business Operations	
Tec Laboratories Inc.		083647792	manufacture(51879-802)	

Revised: 10/2023 Tec Laboratories Inc.