

TECNU IVY COMPLETE KIT- ivy treatment
Tec Laboratories 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.

Diphenhydramine HCL 2%

Purpose Topical analgesic/antihistamine

for the temporary relief of pain and itching associated with:

- minor burns • sunburn • minor cuts • scrapes • insect bites
- minor skin irritations
- rashes due to poison ivy, poison oak and poison sumac

Do not use:

- on large areas of the body
- with any other product containing diphenhydramine, even on taken by mouth

Ask a doctor before use:

- on chicken pox
- on measles

Keep out of reach of children.

- if swallowed, get medical help or contact a poison control center right away

When using this product:

- 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 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 bandage; if bandage 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



TECNU IVY COMPLETE KIT

ivy treatment kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51879-400
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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NDC 51879-400	1	1 CARTON, Three 2 oz. Cleanse, One 4 oz. Treat, Three Individually Wrapped Detox Wipes		
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1	NDC:51879-400-04	1 in 1 CARTON; Type 0: Not a Combination Product	01/16/2023
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Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	113.4 g

Part 1 of 1

TECNU TREAT

diphenhydramine hydrochloride gel

Product Information

Item Code (Source)	NDC:51879-410
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ZINC ACETATE (UNII: FM5526K07A)	
WATER (UNII: 059QF0K00R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51879-410-04	113.4 g in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not	part 349	01/16/2023	

final	part348	01/16/2023	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/16/2023	

Labeler - Tec Laboratories Inc. (083647792)

Establishment

Name	Address	ID/FEI	Business Operations
Tec Laboratories, Inc.		083647792	manufacture(51879-400)

Revised: 1/2023

Tec Laboratories Inc.