MAXIMUM STRENGTH ANTI-ITCH- hydrocortisone 1% spray
Quality Choice

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.

Drug Facts

Active ingredient	**Purpose**
Hydrocortisone - 1.00%	Anti-itch

Uses

Temporarily relieves itching associated with minor skin irritation and rashes due to:

- eczema
- poison ivy, oak and sumac
- cosmetics
- psoriasis
- soaps and detergents
- jewelry
- insect bites
- seborrheic dermatitis

Warnings

For external use only

Flammable: Do not use while smoking or near heat or flame

When using this product

Avoid contact with the eyes. If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, stop use of this product and do not begin use of any other hydrocortisone product unless you have consulted a doctor.
Do not use for the treatment of diaper rash. Consult a doctor.
Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120˚F.F

Ask doctor before use if you are using any other hydrocortisone product

Keep out of reach of the children

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

Directions

- shake well
- 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: ask a doctor
- to apply to face, spray into palm of hand and gently apply

Inactive ingredients

Citric Acid, Disodium EDTA, Glycerin, Poloxamer 188, Polysorbate 20, SD Alcohol 40-B, Water

MAXIMUM STRENGTH ANTI-ITCH

hydrocortisone 1% spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-782
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Hydrocortisone (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	Hydrocortisone	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Glycerin (UNII: PDC6A3C0OX)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Polysorbate 20 (UNII: 7T1F30V5YH)	
ALCOHOL (UNII: 3K9958V90M)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-782-03	85 g in 1 CAN; Type 0: Not a Combination Product	04/07/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/07/2014	

Labeler - Quality Choice (011920774)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(63868-782) , label(63868-782)

Revised: 6/2018 Quality Choice