# WINCO MAXIMUM STRENGTH HYDROCORTISONE- hydrocortisone cream WINCO FOODS, LLC

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.

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## Winco Hydrocortisone Plus Cream 1oz 24197 ZDP

## **Active ingredient Purpose**

Hydrocortisone 1%......Anti-itch

#### Uses

temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:

- eczema
- psoriasis
- jewelry
- insect bites
- soaps
- cosmetics
- detergents
- seborrheic dermatitis
- poison ivy, oak, sumac
- temporarily relieves external anal and genital itching
- other uses of this product should only be under the advice and supervision of a doctor

### Warnings

For external use only

#### Do not use

- in the genital area if you have a vaginal discharge. Consult a doctor
- for the treatment of diaper rash. Consult a doctor.
- more than directed unless directed by a doctor

## When using this product

- avoid contact with eyes
- do not put directly into the rectum by using fingers or any mechanical device or applicator

## 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, and do not begin use of any other hydrocortisone product unless you have asked a doctor
- rectal bleeding occurs

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

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

#### **Directions**

- for itching of skin irritation, inflammation, and rashes:
- 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
- for external anal and genital itching, adults:
- when practical, clean the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a soft cloth before applying
- apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

#### Other information

• store at room temperature 20-25°C (68-77°F)

## **Inactive ingredients**

.alpha.-tocopherol acetate, aole vera leaf, aluminium sulfate octadecahydrate, calcium acetate monohydrate, cetostearyl alcohol, cetyl alcohol, corn oil, dextrin, glycerin, isopropyl palmitate, light mineral oil, maltodextrin, methylparaben, petrolatum, propylene glycol, propylparaben, purified water, sodium cetostearyl sulfate, sodium lauryl sulfate, vitamin a palmitate, white wax

## Distributed by:

Winco Foods, LLC, BOISE, ID 83704



## WINCO MAXIMUM STRENGTH HYDROCORTISONE

#### **Product Information**

**Inactive Ingredients** 

METHYLPARABEN (UNII: A2I8C7HI9T)
CETYL ALCOHOL (UNII: 936JST6JCN)

ALOE VERA LEAF (UNII: ZY81Z83H0X)

ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)

WATER (UNII: 059QF0KO0R)

GLYCERIN (UNII: PDC6A3C0OX)

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67091-197

Route of Administration TOPICAL

## **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ) HYDROCORTISONE 10 mg in 1 g

## **Ingredient Name** Strength MALTODEXTRIN (UNII: 7CVR7L4A2D) **SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)** VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) PROPYLPARABEN (UNII: Z8IX2SC10H) WHITE WAX (UNII: 7G1J5DA97F) **SODIUM LAURYL SULFATE (UNII: 368GB5141))** .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) **ALUMINIUM SULFATE OCTADECAHYDRATE (UNII: TCS9L00G8F)** CALCIUM ACETATE MONOHYDRATE (UNII: 7ZA48GIM5H) CORN OIL (UNII: 8470G57WFM) ICODEXTRIN (UNII: 2NX48Z0A9G) LIGHT MINERAL OIL (UNII: N6K5787QVP) PETROLATUM (UNII: 4T6H12BN9U) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)

Packaging								
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:67091-197- 28	1 in 1 CARTON	10/12/2020					
1		28 g in 1 TUBE; Type 0: Not a Combination Product						

Marketing In	Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC						

OTC monograph not final	part348	10/12/2020	

## Labeler - WINCO FOODS, LLC (056098817)

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