

**HYDROCORTISONE- hydrocortisone ointment**  
**TRIFECTA PHARMACEUTICALS USA LLC**

-----  
**Always Save Hydrocortisone OINTMENT 1%**

**Active ingredient**

Hydrocortisone 1%

**Purpose**

Anti-itch

**Keep out of the reach of children**

If swallowed, get medical help or contact a Poison Control Center immediately.

**Uses**

temporary relief of itching associated with minor skin irritations, inflammation and rashes due to:

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

**Warnings**

- **for external use only**

***Directions***

Adults and children 2 years 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

For External and anal itching:

Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly or by patting or blotting with toilet tissue or a soft cloth before application of this product.

Children under 12 years of age with external anal itching: consult a doctor.

**Inactive ingredients** Light Mineral Oil, Petrolatum

## **Do Not Use**

Do Not use

- For the treatment of diaper rash, consult a doctor
- for external genital itching if you have a vaginal discharge, consult a doctor.

## **Other Information**

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

## **Distributed By**

Proudly Distributed By:

Associated Wholesale Grocers Inc.

Kansas City, Kansas 66106

## **Stop using this product and ask a doctor if**

- Conditions worsen
- Symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and do not begin use any other hydrocortisone product unless directed by a doctor.

## **When Using This Product**

- Avoid contact with eyes
- Do not begin the use of any other hydrocortisone product unless you have consulted a doctor.
- For external genital, feminine and anal itching do not exceed the recommended daily dosage unless directed by a doctor.
- In case of bleeding, stop use, consult a doctor.
- Do not put this product into the rectum by using fingers or any mechanical device or applicator.

## **Questions:**

Call 1-800-883-0085

## **Packaging**

OUTSIDE BOX





## INNER TUBE

			
<p>NET WT 1 OZ. (28 g)</p>		<p>RELIEF OF MINOR SKIN IRRITATIONS, ITCHING AND RASHES</p>	
<p><b>Active ingredient</b> Hydrocortisone 1%</p>	<p><b>Purpose</b> Anti-itch</p>	<p>within a few days, discontinue use of this product and do not begin use of any other hydrocortisone product unless directed by a doctor.</p>	<p><b>Keep out of the reach of children.</b> If swallowed, get medical help or contact a Poison Control Center immediately.</p>
<p><b>Uses</b> For temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to:</p> <ul style="list-style-type: none"> <li>• eczema • insect bites • poison ivy • poison oak • poison sumac • soaps • detergents</li> <li>• cosmetics • jewelry • seborrheic dermatitis • psoriasis</li> <li>• external feminine, genital and anal itching</li> </ul> <p>Other use of this product should be only under the advice and supervision of a doctor.</p>	<p><b>Directions</b> Adults and children 2 years 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. <b>For external and anal itching:</b> • adults: when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly or by patting or blotting with toilet tissue or a soft cloth before application of this product. • children under 12 years of age with external anal itching: consult a doctor.</p>	<p><b>Other information</b> Store at controlled room temperature 20° - 25°C (68° - 77°F).</p>	<p><b>Inactive ingredients</b> Light mineral oil, Petrolatum.</p>
<p><b>Warnings:</b> For external use only Do not use • for the treatment of diaper rash, consult a doctor. • for external genital itching if you have a vaginal discharge, consult a doctor. <b>When using this product:</b> • avoid contact with the eyes. • do not begin the use of any other hydrocortisone product unless you have consulted a doctor. • do not begin the use of any other hydrocortisone product unless you have consulted a doctor. • do not put this product into the rectum by using fingers or any mechanical device or applicator.</p>	<p><b>Stop using this product and ask a doctor if:</b> • symptoms persist for more than 7 days or clear up and occur again within a few days.</p>	<p><b>Questions?</b> Call 1-800-883-0085</p>	<p><b>Questions?</b> Call 1-800-883-0085</p>
<p>PROUDLY DISTRIBUTED BY: ASSOCIATED WHOLESALE GROCERS, INC. KANSAS CITY, KANSAS 66106</p>			

# HYDROCORTISONE

hydrocortisone ointment

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69396-149
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PETROLATUM (UNII: 4T6H12BN9U)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-149-01	1 in 1 BOX	03/14/2024	
1		28 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	03/10/2024	

**Labeler** - TRIFECTA PHARMACEUTICALS USA LLC (079424163)

Revised: 3/2024

TRIFECTA PHARMACEUTICALS USA LLC