

WELLY ITCH FIX- hydrocortisone anti itch cream cream

Welly Health PBC

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

Hydrocortisone 1.0%

Purpose

Anti-itch

Uses

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

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

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.

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.

Stop use and ask a doctor if

- If condition worsens

- 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 of any other hydrocortisone product unless directed by a doctor.

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

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 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.

Other information

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

Inactive ingredients

Aloe barbadensis leaf extract, Benzyl alcohol, Cetareth-20, Cetaryl alcohol, Cetyl palmitate, Glycerin, Isopropyl myristate, Isostearyl neopentanoate, Methylparaben, PEG-40 stearate, Propylene glycol, Purified water

Principal Display Panel – Can Label

Welly First Aid Itch Fix

NDC 72663-155-50

Hydrocortisone 1% Anti-itch Cream

2 tubes -0.57 oz(16g) Total Net Wt 1.14oz (32g)

<p>Drug Facts</p> <p>Active Ingredients (in each gram)</p> <p>Hydrocortisone 1.0% Purpose</p> <p>Anti-itch</p> <p>Uses for temporary relief of itching associated with minor skin irritations, inflammation, and rashes</p> <p>Warnings For external use only</p> <p>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. 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. ▶</p>	<p style="text-align: center;">FIRST AID</p> <p style="text-align: center;">welly</p> <p style="text-align: center;">Itch Fix</p> <p style="text-align: center;">1% HYDROCORTISONE ANTI-ITCH CREAM</p> <div style="text-align: center;">  <p>COUNT 2</p> </div> <p style="text-align: center;">2 TUBES – 0.57 oz (16 g) TOTAL NET WT 1.14 oz (32 g)</p>	<p>Recycle me!</p> <p>Distributed by: Welly Health PBC Minneapolis, MN 55402 1-833-8E-WELLY</p> <p>Welly™ www.GetWelly.com Products of USA with globally sourced materials RKT18SHE</p> <p>WLY1023</p> <div style="text-align: center;">  <p>3 72663 15550 3</p> </div>	<p>Warnings continued • do not put this product into the rectum by using fingers or any mechanical device or applicator.</p> <p>Stop use and ask a doctor if condition worsens, symptoms persist for more than 7 days, or if you have a fever, rash, or other symptoms.</p> <p>Use of this product and do not begin use of any other hydrocortisone product unless directed by a doctor. Keep out of the reach of children. If swallowed get medical help or contact a Poison Control Center immediately.</p> <p>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 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.</p> <p>Other Information: Store at a controlled room temperature 68°-77° (20°-25°C).</p> <p>Inactive ingredients Aloe Barbadensis Leaf Juice, Aluminum Sulfate, Beeswax, Calcium Acetate, Cetaryl Alcohol, Dextrin, Glycerin, Maltodextrin, Methylparaben, Mineral Oil, Petrolatum, Propylparaben, Sodium Cetaryl Sulfate, Sodium Lauryl Sulfate, Water (Purified)</p>
---	---	---	--

Principal Display Panel – 0.57oz Tube Label

NDC 72663-155-50 Welly First Aid Itch fix

Hydrocortisone 1% Anti-itch Cream Net Wt. 0.57 oz (16g)



NET WT 0.57 oz (16 g)

Active ingredient: Hydrocortisone 1.0% **Purpose:** Anti-itch Uses for temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to • eczema • insect bites • poison ivy • poison oak • poison sumac • soaps • detergents • cosmetics • jewelry • seborrheic dermatitis • psoriasis • 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. 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. **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. **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, discontinue use of this product and do not begin use of any other hydrocortisone product unless directed by a doctor. **Keep out of the reach of children.** If swallowed get medical help or contact a Poison Control Center immediately. **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 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. **Other information** • Store at a controlled room temperature 68°-77°F (20°-25°C)
Distributed by: Welly Health PBC Minneapolis, MN 55402 1-833-BE-WELLY

WELLY ITCH FIX

hydrocortisone anti itch cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72663-155
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: W14X0X7BPJ) (Hydrocortisone - UNII:W14X0X7BPJ)	Hydrocortisone	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM SULFATE (UNII: 34S289N54E)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CALCIUM ACETATE (UNII: Y882YXF34X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ICODEXTRIN (UNII: 2NX48Z0A9G)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
METHYL PARABEN (UNII: A218C7H19T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72663-155-50	2 in 1 CAN	02/22/2019	
1		16 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 not final	part348	02/22/2019	

Labeler - Welly Health PBC (116766884)**Registrant** - Welly Health PBC (116766884)**Establishment**

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(72663-155)