

ITCH FIXER- hydrocortisone 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.

Itch Fixer

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

For temporary relief of itching associated with minor skin irritations 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 • 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 • If symptoms persist for more than 7 days or clear up and reoccur, 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.

- Do not use if pregnant or breastfeeding.

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 with external anal itching: consult a doctor.

Other information

Store at a controlled room temperature 68°–77°F (20°–25°C).

Inactive Ingredients

Aqua, Aloe Vera Oil, Benzoic Acid, Cetostearyl Alcohol, Glyceryl Stearate, Jojoba Oil, Polysorbate 80, Oleyl Alcohol, Sorbic Acid, Sorbitan Monooleate

1% Hydrocortisone Anti-Itch Cream

FREE FROM

x

Petrolatum

Parabens

Sulfates

Mineral Oil

Fragrance

FRAGRANCE FREE

KID FRIENDLY

MADE WITH SQUEAKY CLEAN INGREDIENTS FOR HAPPY HEALING

SQUEAKY CLEAN FIRST AID

Formulated with naturally derived plant-based ingredients

ALOE VERA known to help soothe skin

JOJOBA OIL known to help moisturize skin

**HELPS PROVIDE TEMPORARY ITCH RELIEF FROM
skin irritation**

rashes

insect bites

poison ivy

eczema

Packaging is recyclable.

Distributed by Welly Health PBC

Minneapolis, MN 55402

1-833-BE-WELLY | getwelly.com

Product of USA and Canada with globally sourced materials.

Packaging



ITCH FIXER

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72663-493
Route of Administration	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
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
JOJOBA OIL (UNII: 724GKU717M)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
SORBIC ACID (UNII: X045WJ989B)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72663-493-66	1 in 1 CARTON	10/01/2021	
1		57 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	10/01/2021	

Labeler - Welly Health PBC (116766884)

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Welly Health PBC