

DR. SHEFFIELD HYDROCORTISONE ANTI ITCH- hydrocortisone cream
Sheffield Pharmaceuticals LLC

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

Inactive ingredients

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

Principal Display Panel - 1oz Carton Label

Compare to the active ingredient of Cortizone●10®*

NDC 11527-052-55

Hydrocortisone MAXIMUM STRENGTH

Net Wt. 1 oz (28g) Hydrocortisone 1% Anti-itch Cream

Dr. Sheffield's

SHEAF-FIELD™

Made in the USA

Compare to the active ingredient of Cortizone•10®*

Dr. Sheffield's

Made in the USA

Hydrocortisone

MAXIMUM STRENGTH

Hydrocortisone 1% Anti-itch Cream

For Temporary Relief of:

- Eczema
- Insect Bites
- Poison Ivy, Oak & Sumac
- Soaps & Detergents
- Jewelry & Cosmetics
- Seborrheic Dermatitis & Psoriasis

Helps Relieve Itching Fast

Helps relieve itching associated with minor skin irritations, inflammation and rashes

Dr. Sheffield's

Compare to the active ingredient of Cortizone•10®*

NDC 11527-052-55



Hydrocortisone

MAXIMUM STRENGTH

Made in the USA

Net Wt. 1 oz (28g) Hydrocortisone 1% Anti-itch Cream



Dr. Washington Wentworth Sheffield invented toothpaste in 1850 and started producing his "Analgic Balm" ointment and "Crema Dentifrice" in his laboratory behind his house. This was the beginning of today's Sheffield Pharmaceuticals. Another first occurred in 1876, when he and his son, Dr. Lucius Tracy Sheffield, were the first to package toothpaste, cream and ointments into tubes. Many of today's leading brands were first produced in our laboratory. To this day, Sheffield Pharmaceuticals continues to excel in product development; our long history of product innovation and technical expertise assures you of the consistently high quality and effectiveness that you need and deserve.



SHEFFIELD PHARMACEUTICALS | www.sheffield-pharmaceuticals.com | New London, CT 06320 USA | Questions? 1-800-222-1087 | Made in the USA

*This product is not manufactured or distributed by © CHATTEM, INC., owner of the registered trademark Cortizone•10®

Drug Facts	<p>Active ingredient Hydrocortisone 1.0% Anti-itch</p> <p>Purpose Stop use and ask a doctor if: • it condition worsens • symptoms persist • more than 7 days of over use occur while using any other hydrocortisone product unless directed by a doctor.</p> <p>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 • genital and anal itching.</p> <p>Warnings For external use only. Do not use • for the treatment of deeper 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, genital 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.</p>
Drug Facts (continued)	<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 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 20° - 25°C (68° - 77°F).</p> <p>Inactive ingredients Aloe barbadensis leaf extract, Benzyl alcohol, Carbeth-20, Cetaryl alcohol, Cetyl palmitate, Glycerin, Isopropyl myristate, Isostearyl isocaproate, Methylparaben, PEG-40 stearate, Polyethylene glycol, Purified water.</p>

Hydrocortisone

Dr. Sheffield's

Made in the USA



Dr. Sheffield's
Hydrocortisone
Hydrocortisone 1%
Anti-itch Cream



Principal Display Panel - 1oz Tube Label


NDC 11527-052-55

Hydrocortisone MAXIMUM STRENGTH

Net Wt. 1 oz (28g) Hydrocortisone 1% Anti-itch Cream

Dr. Sheffield's
SHEAF-FIELD™
 Made in the USA

SHEFFIELD PHARMACEUTICALS www.sheffield-pharmaceuticals.com
 New London, CT 06320 USA (Questions?) 1-800-222-1087 Made in the USA




Dr. Sheffield's
Made in the USA

NDC 11527-052-55
MAXIMUM STRENGTH

Hydrocortisone

Net Wt. 1 oz (28g) Hydrocortisone 1% Anti-itch Cream

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


 2502043

DR. SHEFFIELD HYDROCORTISONE ANTI ITCH

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11527-052
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

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11527-052-55	1 in 1 CARTON	07/10/2007	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:11527-052-51	1 in 1 CARTON	07/10/2007	
2		14 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	07/10/2007	

Labeler - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(11527-052)

Revised: 10/2023

Sheffield Pharmaceuticals LLC