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

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## **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
- iewelry
- 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 analitching 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, Ceteareth-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<sup>TM</sup>

Made in the USA



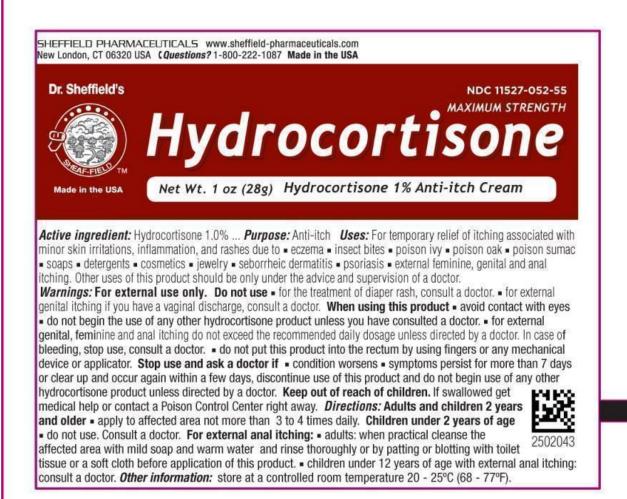
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## DR. SHEFFIELD HYDROCORTISONE ANTI ITCH

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	<b>Basis of Strength</b>	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: ORE8K4LNJS)		
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					
Na me	Address	ID/FEI	<b>Business Operations</b>		
Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(11527-052)		

Revised: 10/2023 Sheffield Pharmaceuticals LLC