

**HYDROCORTISONE MAXIMUM STRENGTH- hydrocortisone cream**  
**medsource pharmaceuticals**

*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.*

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**Hydrocortisone Cream**

***Drug Facts***

***Active ingredient***

Hydrocortisone, USP 1%

***Purpose***

Anti-itch

***Uses***

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

- eczema
- insect bites
- poison ivy
- poison oak
- poison sumac
- soaps
- jewelry
- detergents
- cosmetics
- psoriasis
- seborrheic dermatitis
- for external genital, feminine 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 external feminine itching if you have a vaginal discharge. Consult a doctor.
- for the treatment of diaper rash. Consult a doctor.

**When using this product**

- avoid contact with the eyes
- do not begin the use of any other hydrocortisone product unless directed by a doctor
- for external anal itching: •do not use more than directed unless directed by 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**

- symptoms last for more than 7 days
- the condition gets worse
- symptoms clear up and occur again in a few days
- rectal bleeding occurs, consult doctor promptly

## 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 of age 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, clean the affected area with mild soap and warm water, rinse thoroughly, gently dry by patting or blotting with toilet issue or a soft cloth before application of this product

Children under 12 years of age: consult a doctor

### Other information

- Store at room temperature 59°-86°F (15°-30°C). Protect from freezing.
- Before using any medication, read all label directions. Keep carton, it contains important information.

### Inactive ingredients

cetyl alcohol, glyceryl stearate, isopropyl myristate, methylparaben, polyoxyl 40 stearate, polysorbate 60, propylene glycol, propylparaben, purified water, sorbic acid, sorbitan monostearate, stearyl alcohol, white wax. May contain citric acid or sodium citrate solution to adjust pH.

### Questions?

1-800-432-8534 between 9 am and 4 pm EST, Monday–Friday.

### PRINCIPAL DISPLAY PANEL



## HYDROCORTISONE MAXIMUM STRENGTH

hydrocortisone cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45865-630(NDC:0472-0343)
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SORBIC ACID (UNII: X045WJ989B)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WHITE WAX (UNII: 7G1J5DA97F)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45865-630-01	1 in 1 CARTON	06/01/2018	
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 not final	part348	07/01/1997	

**Labeler** - medsource pharmaceuticals (833685915)**Establishment**

Name	Address	ID/FEI	Business Operations
medsource pharmaceuticals		833685915	repack(45865-630)

Revised: 12/2018

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