HYDROCORTISONE 1%- hydrocortisone 1% cream
ProStat First Aid LLC

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.

2045 Hydrocortisone Cream USP 1%

Active Ingredient

Hydrocortisone USP 1%

Purpose

Antipruritic (Anti-Itch)

Use(s)

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, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis, and for external genital, feminine, and anal itching

Warnings

For Exteranl Use Only

If pregnant or breast-feeding

ask a health professional before use

Do not use

• In the eyes • For diaper rash • For external genital or feminine itching if you have a vaginal discharge • More than the recommended daily dosage unless directed by a doctor • In the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

• Condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days (do not continue to use this or any other hydrocortisone product for longer than 7 days) • Bleeding occurs due to anal itching

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) 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: Consult a doctor.

• When used for anal itching, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry, patting or blotting with bathroom tissue or soft cloth before applying. Children under 12: Consult a doctor before using for anal itching.

Other Information

• Store at room temperature 15º-30ºC (59º-86ºF) • Avoid excessive heat • Tamper Evident. Do not use if packet is torn, cut, or opened.

Inactive Ingredients

Cetostearyl Alcohol, Glyceryl Monostearate SE, Methylchloroisothiazolinone, Propylene Glycol, Purified Water, Stearic Acid, Triethanolamine, White Petrolatum

Questions?

1-888-900-2920 Monday - Friday, 8AM - 4PM PST.

Label

Hydrocortisone Cream USP 1%

HYDROCORTISONE 1%

hydrocortisone 1% cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58228-2045
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**
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

WHITE PETROLATUM (UNII: B6E5W8RQJ4)	

Product Characteristics

Color		**Score**	
Shape	FREEFORM	**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58228-2045-2	1800 in 1 CASE	04/10/2023	
1	NDC:58228-2045-1	25 in 1 BOX		
1		0.9 g in 1 PACKET; 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	04/10/2023	

Labeler - ProStat First Aid LLC (061263699)

Revised: 3/2023

ProStat First Aid LLC