THERA PLUS MAXIMUM STRENGTH HYDROCORTISONE- hydrocortisone cream Fourstar Group USA, Inc

Thera Plus Maximum Strength Hydrocortisone Cream

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

• temporarily relieves itching associated with minor skin irritations, inflammation and rashes due to: • eczema • psoriasis • poison ivy,oak, sumac • insect bites • detergents • jewelry • cosmetics • soaps • seborrheic dermatitis • temporarily relieves external anal and gential itching • other uses of this product should be under advice and supervision of a doctor

Warnings

For external use only.

Do not use

• in the genital area 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 eyes. • do not use more than directed unless told to do so by a doctor. • do not put directly into the rectum by using fingers or any mechanical device or applicator.

Stop use and ask a doctor if

• condition worsens, symptoms persists for more than 7 days or clear up and occur again within a few days, and do not begin use of any other hydrocortisone product unless you have asked a doctor • rectal bleeding occurs

Keep out of reach of children.

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

Directions

• for itching of skin irritation, inflammation, and rashes: • 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, ask a doctor • for external anal and genital itching • adults: when practical, clean the affected area with mild soap and warm water and rinse thoroughly • gently dry by patting or blotting with toilet tissue or soft cloth before applying • apply to affected area not more than 3 to 4 times daily • children under 12 years of age: ask a doctor

Other information

• store at room temperature 68 °- 77° F (20°-25°C).

Inactive ingredients

ceteareth-20, cetearyl alcohol, ethylhexylglycerin, glycerin, glyceryl stearate, mineral oil, phenoxyethanol, water, white petrolatum

Questions?

1-800-639-3803Weekdays 9 AM to 4 PM EST

Package Labeling:





THERA PLUS MAXIMUM STRENGTH HYDROCORTISONE

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80684-197
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		
CETEARETH-20 (UNII: YRC528SWUY)			
CETEARYL ALCOHOL (UNII: 2DMT128M1S)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
GLYCERIN (UNII: PDC6A3C0OX)			
GLYCERYL STEARATE (UNII: 2300U9XXE4)			
MINERAL OIL (UNII: T5L8T28FGP)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
WATER (UNII: 059QF0KO0R)			
WHITE PETROLATUM (UNII: B6E5W8RQJ4)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:80684-197- 00	6 in 1 BOX	11/20/2025		
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 Drug	M017	11/20/2025		

Labeler - Fourstar Group USA, Inc (140099503)

Registrant - Fourstar Group USA, Inc (140099503)

Revised: 12/2025 Fourstar Group USA, Inc