

THERA PLUS- hydrocortisone cream
Zhejiang Jingwei Pharmaceutical Co., Ltd.

Drug Facts

aloe barbadensis leaf extract, glycerin, glycerol stearate, methylparaben, mineral oil, petrolatum, propylparaben, sodium lauryl sulfate, stearyl alcohol, water **Inactive**

Ingredients

Active Ingredient

Hydrocortisone, USP 1%

Purpose

Anti-itch

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

- 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

. If swallowed, get medical help or contact a Poison Control Center right away. **Keep out of reach of children**

Warnings for external use only

Do not use

-in genital area if you have a vaginal discharge. Consult a doctor

-for the treatment of diaper rash. Consult a doctor

Stop use and ask a doctor if

-symptoms last for more than 7 days

-the condition gets worse

-symptoms clear up and then occur again within a few days

-rectal bleeding occurs

When using this product

-avoid contact with eyes

-do not use more than directed unless directed by a doctor

-do not put this product into the rectum by using fingers or any other mechanical device or applicator

Directions

for itching of skin irritation, inflammation and rashes:

-adults and children 2 years of age and older: apply to the affected area not more than 3 to 4 times daily

-for children under 2 years of age: ask a doctor

for external anal and genital itching, adults:

-clean the affected area with mild soap and warm water and rinse clean.

-dry the affected area before applying

-apply to the affected area not more than 3 to 4 times daily

-children under 12 years of age: ask a doctor



hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55621-001
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55621-001-01	28 g in 1 TUBE; Type 0: Not a Combination Product	03/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/01/2013	

Labeler - Zhejiang Jingwei Pharmaceutical Co., Ltd. (530876549)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Jingwei Pharmaceutical Co., Ltd.		530876549	manufacture(55621-001)