MEIJER MAX. STRENGTH ANTI-ITCH CREAM INTENSIVE HEALING FORMULAhydrocortisone cream MEIJER, INC.

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.

Meijer Max. Strength Anti-Itch Cream Intensive Healing Formula 2oz ZDP Active Ingredient Purpose

Hydrocortisone 1%......Anti-itch

Uses

temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:

- eczema
- psoriasis
- jewelry
- insect bites
- soaps
- cosmetics
- detergents
- seborrheic dermatitis
- poison ivy, oak sumac

temporarily relieves external anal and genital itching

other uses of this product should only be under the 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.
- more than directed unless directed by a doctor

When using this product

- avoid contact with eyes
- 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 persist 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

If pregnant or breast-feeding, ask a health professional before use.

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

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: 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 a 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 20-25°C (68-77°F)

Inactive ingredients aloe vera leaf, .alpha.-tocopherol acetate, benzyl alcohol, cetyl alcohol, dimethicone 350, edetate disodium, gelatin hydrolysate, glycerin, glyceryl stearate/peg-100 stearate, magnesium ascorbyl phosphate, matricaria chamomilla flowering top, menthyl lactate, methyl gluceth-20, methylparaben, pretrolatum, polysorbate 60, propylene glycol, propylparaben, purified water, steareth-2, steareth-21, stearyl alcohol, vitamin a palmitate



FORMULA

hydrocortisone cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41250-259

Route of Administration TOPICAL

Active Ingredient/Active Moiety

	Ingredient Name		Basis of Strength	Strength
	HYDROCORTISONE (LINII: W4X0X7RPI) (HYDROCORTISONE - LINII: W4X0X7RPI)	HYDROCORTISONE	10 mg in 1 g	

Inactive Ingredients Ingredient Name Strength ALOE VERA LEAF (UNII: ZY81Z83H0X) MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5) MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I) METHYLPARABEN (UNII: A2I8C7HI9T) POLYSORBATE 60 (UNII: CAL22UVI4M) **STEARETH-21** (UNII: 53J3F32P58) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0KO0R) VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) **DIMETHICONE 350** (UNII: 2Y53S6ATLU) GELATIN HYDROLYSATE (PORCINE SKIN, MW 3000) (UNII: 0K9R94573C) CETYL ALCOHOL (UNII: 936|ST6|CN) EDETATE DISODIUM (UNII: 7FLD91C86K) GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947) METHYL GLUCETH-20 (UNII: J3QD0LD11P) .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) GLYCERIN (UNII: PDC6A3C0OX) BENZYL ALCOHOL (UNII: LKG8494WBH) PETROLATUM (UNII: 4T6H12BN9U) STEARETH-2 (UNII: V56DFE46J5) STEARYL ALCOHOL (UNII: 2KR89I4H1Y) MATRICARIA CHAMOMILLA FLOWERING TOP (UNII: 3VNC7T6Z02)

F	Packaging						
#	tem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:41250-259- 57	1 in 1 CARTON	07/16/2020				
1		57 g in 1 TUBE; Type 0: Not a Combination Product					

Marketing	Information

PROPYLPARABEN (UNII: Z8IX2SC1OH)

Marketing Application Number or Monograph Marketing Start Marketing End
Category Citation Date Date

OTC monograph not final	part348	07/16/2020	

Labeler - MEIJER, INC. (006959555)

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