

**AVON HEXASHIELD ANTI ITCH CREAM WITH HEALING ALOE- hydrocortisone cream
Tai Guk Pharm. Co., Ltd.**

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.

AVON HeXashield Anti Itch Cream with Healing Aloe

Active Ingredient

Hydrocortisone 0.5 %

Purpose

Anti-Itch

Uses

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

- eczema
- psoriasis
- poison ivy, oak or sumac
- insect bites
- detergents
- jewelry
- cosmetics
- soaps
- seborrheic dermatitis
- temporarily relieves external anal and genital itching
- other uses of this product should be only under the advice and supervision of 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 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

Do not use this product and ask a doctor

- if you have a vaginal discharge
- before treating diaper rash
- before using on children under 2 years of age

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center 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
- Lot No. & Exp. Date: see box or crimp of tube

Inactive Ingredients

aloe vera leaf, butylated hydroxytoluene, ceteth-20, cetyl alcohol, methylparaben, mineral oil, propylparaben, sorbitan monostearate, stearyl alcohol, water

Questions or comments?

Call toll free **1-800-FOR-AVON**

www.avon.com

Principal Display Panel

HeXasheild

AVON

Relieves skin irritation and rashes due to

- Eczema - Seborrheic Dermatitis - Detergents
- Psoriasis - Poison ivy, Oak & sumac - Jewelry
- Insect bites - Soaps - Cosmetics

HeXashield

ANTI ITCH CREAM

WITH HEALING ALOE

Fragrance Free plus Soothing Aloe

0.5% hydrocortisone cream Regular strength

ANTI ITCH CREAM WITH HEALING ALOE
Regular Strength Hydrocortisone 0.5%

Drug Facts

Active ingredient	Purpose
Hydrocortisone 0.5%	Anti-itch

Uses temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to: eczema psoriasis poison ivy, poison oak and poison sumac insect bites detergents jewelry cosmetics soaps seborrheic dermatitis 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.

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 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

Do not use this product and ask a doctor ■ if you have a vaginal discharge ■ before treating diaper rash ■ before using on children under 2 years of age
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
 for itching of skin irritation, inflammation, and rashes :
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Questions or comments? Call toll free 1-800-FOR-AVON www.avon.com

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TP21640

AVON HEXASHIELD ANTI ITCH CREAM WITH HEALING ALOE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43136-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SORBITAN MONOSTEARATE (UNII: NVZ410H58X)	
CETETH-20 (UNII: I835H2IHHX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MINERAL OIL (UNII: T5L8T28FGP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43136-103-01	1 in 1 CARTON	07/31/2019	
1		57 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	07/31/2019	

Labeler - Tai Guk Pharm. Co., Ltd. (689060246)

Establishment

Name	Address	ID/FEI	Business Operations
Tai Guk Pharma. Co., Ltd.		689060246	manufacture(43136-103)

Revised: 7/2019

Tai Guk Pharm. Co., Ltd.