

HYDROCORTISONE MAXIMUM STRENGTH- hydrocortisone ointment
Unipack, 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.

Avedana[®] Maximum Strength Hydrocortisone Ointment

Active Ingredient

Hydrocortisone, USP 1%

Purpose

Anti-itch

Uses

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,
- 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

Warnings

For external use only

Do not use

- for external feminine itching 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 the eyes, do not begin the use of any other hydrocortisone product unless directed by a doctor, for external anal itching: do not use more than directed unless directed by a doctor, do not put this product into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

symptoms last for more than 7 days, the condition gets worse, symptoms clear up and occur again in a few days, rectal bleeding occurs, consult doctor promptly

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center 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

- do not use, consult a doctor.

For external anal itching

Adults: when practical, clean the affected area with mild soap and warm water, rinse thoroughly, gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.

Children under 12 years of age:

- consult a doctor.

Other information

- Storage temperature: not to exceed 30°C (86°F).
- Before using any medication, read all label directions. Keep carton, it contains important information.

Inactive Ingredients

mineral oil, white petrolatum

Avedana[®] Maximum Strength Hydrocortisone Ointment | 1oz Tube Label

MAXIMUM STRENGTH

Hydrocortisone Ointment, USP 1%

Anti-Itch Ointment

• Relieves itches & rashes



NET WT 1 OZ (28 g)

Drug Facts **Active ingredient Hydrocortisone** Hydrocortisone, USP 1% **Purpose** Anti-itch

Uses 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 ■ 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

Warnings **For external use only** **Do not use** ■ for external feminine itching if you have vaginal discharge. Consult a doctor. ■ for the treatment of diaper rash. Consult a doctor.

When using this product ■ avoid contact with eyes ■ do not begin the use of any other hydrocortisone product unless directed by a doctor ■ for external anal itching: ■ do not use more than directed unless directed by a doctor ■ do not put this product into the rectum by using fingers or any mechanical device or applicator

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Inactive ingredients mineral oil, white petrolatum

UNIPACK, INC., PITTSBURGH, PA 15239 USA

Questions? 724-733-7381

INFO@UNIPACKING.COM, 724-733-7381

Avedana® Maximum Strength Hydrocortisone Ointment | 1oz Carton Label



MAXIMUM STRENGTH

Hydrocortisone Ointment, USP 1%

For the temporary relief of itches & rashes due to:

- Insect bites • Eczema • Seborrheic dermatitis
- Poison ivy, oak & sumac
- External genital, feminine & anal itching
- Detergents, jewelry & cosmetics

Compare to Cortizone-10® active ingredient

Relieves itches & rashes.



MAXIMUM STRENGTH

Hydrocortisone Ointment, USP 1%

Anti-Itch Ointment

NET WT 1 OZ (28 g)

THIS FLAP IS FOR IMPRINT AREA; NO ART, TEXT, OR COLOR HERE

†† This product is not affiliated with, manufactured by, or produced by Chattem, Inc., the owner of Cortizone-10®.

DISTRIBUTED BY:
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(724)733-7381

NDC 43749 251 01



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Purpose Anti-itch

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 ■ jewelry ■ detergents ■ cosmetics ■ psoriasis ■ seborrheic dermatitis

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Do not use ■ For external feminine itching 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 the eyes ■ do not begin the use of any other hydrocortisone product unless prescribed by a doctor ■ Do not use more than directed unless directed by a doctor

Stop use and ask a doctor if
 ■ Symptoms last for more than 7 days
 ■ The condition gets worse
 ■ Rectal bleeding occurs, consult doctor promptly

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

Directions
 Adults and children 2 years of age and older ■ apply to affected area not more than 3 to 4 times daily
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 For external anal itching
 ■ Adults: when practical, clean the affected area with mild soap and warm water, rinse thoroughly, gently dry by patting or blotting with toilet tissue or a soft cloth before application of the product
 Children under 12 years of age ■ consult a doctor

Other information
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Inactive ingredients mineral oil, white petrolatum.

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HYDROCORTISONE MAXIMUM STRENGTH

hydrocortisone ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43749-251
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	0.01 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43749-251-01	1 in 1 CARTON	09/03/2021	
1	NDC:43749-251-03	28 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	09/03/2021	

Labeler - Unipack, Inc. (009248480)

Registrant - ASIAN AEROSOL OAN PRIVATE LIMITED (872341020)

Establishment

Name	Address	ID/FEI	Business Operations
Unipack, Inc.		009248480	label(43749-251)

Establishment

Name	Address	ID/FEI	Business Operations
ASIAN AEROSOL OAN PRIVATE LIMITED		872341020	manufacture(43749-251)

Revised: 9/2021

Unipack, Inc.