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 applicaion of this product.

Children under 12 years of age:

• consult a doctor.

Other information

- Storage temperature: not to exceed 30oC (86oF).
- 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 Avedana' **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 Stop use and ask a doctor if symptoms last for more than 7 days sthe condition gets worse start and ask a doctor if symptoms last for more than 7 days street the condition gets worse start and ask a doctor if 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 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 UNIPACK, N.C., PITTSBURGH, PA 15239 USA Questions? 724-733-7381 NEDØLNIBACKNICCOM (724733-7381)

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 0Z (28 g)

Avedana® ...means no pain!

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

DISTRIBUTED BY: UNIPACK, INC. PITTSBURGH, PA 15239 USA INFO@UNIPACKINC. COM (724)733-7381



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HYDROCORTISONE MAXIMUM STRENGTH

hydrocortisone ointment

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Prod	UCT	Inform	ation

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
ingredient Name	Streng

PETROLATUM (UNII: 4T6H12BN9U)

MINERAL OIL (UNII: T5L8T28FGP)

Product Characteristics

Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

Packaging

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ı	# Item C	ode	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:4374	9-251-	1 in 1 CARTON	09/03/2021	
	1 NDC:4374		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.