AVEDANA HYDROCORTISONE MAXIMUM STRENGTH- hydrocortisone ointment Unipack LLC

Avedana ® Maximum Strength Hydrocortisone Ointment

Drug Facts

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 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 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)

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Avedana® ...means no pain!

> Active ingredient #1 92U ,enosihoooley Drug Facts

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

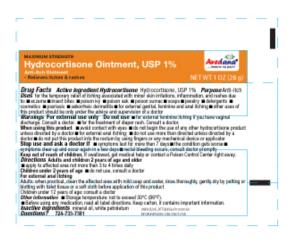
This product is not affiliated with, manufactured by, or produced by Chattem, Inc., the owner of Cortizone 10%.

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



Questions? 724-733-7381	
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Avedana® Maximum Strength Hydrocortisone Ointment | 1oz Tube Label



AVEDANA HYDROCORTISONE MAXIMUM STRENGTH

hydrocortisone ointment

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:43749-250

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII: W4X0X7BPJ) HYDROCORTISONE 0.0102 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:43749-250- 01	1 in 1 CARTON	02/03/2018	
1	NDC:43749-250- 03	28 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

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

Labeler - Unipack LLC (009248480)

Registrant - Unipack LLC (116015769)

Establishment					
Name	Address	ID/FEI	Business Operations		
Unipack LLC		009248480	manufacture(43749-250)		

Revised: 1/2024 Unipack LLC