

**AVEDANA HYDROCORTISONE CREAM WITH ALOE- hydrocortisone cream
Unipack LLC**

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® Hydrocortisone Cream with Aloe - Maximum Strength

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

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). Protect from freezing.
- Before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredients

aloe vera concentrate, benzyl alcohol, cetareth 20, cetaryl alcohol, cetyl palmitate, glycerin, isopropyl myristate, isostearyl neopentanoate, methylparaben, peg-40 stearate, purified water. May contain citric acid or sodium citrate solution to adjust pH.

Questions?

Call 724-733-7381

Avedana® Hydrocortisone Cream with Aloe| 1oz Tube label

MAXIMUM STRENGTH
Hydrocortisone Cream, USP 1% with Aloe
 Anti-Itch Cream
 • Relieves itches & rashes
 NET WT 1 OZ (28 g)

Avedana®

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 application of this product
Children under 12 years of age: consult a doctor
Other information ■ Storage temperature: not to exceed 30°C (86°F). Protect from freezing.
 ■ Before using any medication, read all label directions. Keep carton, it contains important information.
Inactive ingredients aloe vera concentrate, benzyl alcohol, ceteareth 20, cetearyl alcohol, cetyl palmitate, glycerin, isopropyl myristate, isostearyl neopentanoate, methylparaben, peg-40 stearate, purified water. May contain citric acid or sodium citrate solution to adjust pH.
Questions? 724-733-7381

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

MADE IN USA

Avedana® Hydrocortisone Cream with Aloe | 1oz Carton label

MAXIMUM STRENGTH

Hydrocortisone Cream, USP 1% with Aloe

For the temporary relief of itches & rashes due to:
• Insect bites • Eczema • Poison ivy, oak & sumac
• Seborrheic dermatitis • External genital, feminine &
anal itching • Psoriasis • Detergents, jewelry & cosmetics



WITH ALOE

Compare to Cortizone 10®
active ingredient

Relieves itches & rashes.

MAXIMUM STRENGTH

Hydrocortisone Cream, USP 1% with Aloe

Anti-Itch Cream



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

NET WT 1 OZ (28 g)

*This product is not affiliated with, manufactured by, or produced by Chatterm,
the owners of Cortizone 10®.

Distributed By:
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(724) 733-7381

NDC 43749-621-01



Drug Facts

Active ingredient
Hydrocortisone, USP 1%

Uses
For the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to:
• eczema • insect bites • psoriasis • poison ivy • poison oak • poison sumac • soaps
• shingles • dermatitis • contact dermatitis • sunburn • sunburn • sunburn

Warnings
• For external use only.
• Do not use for external genital (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 apply to the face or other sensitive areas unless directed by a doctor.
• Do not use for external genital (you have a vaginal discharge). Consult a doctor. • For the treatment of diaper rash. Consult a doctor.

Directions
• Adults and children 2 years of age and older: Apply to affected area morning and evening. Do not use, consult a doctor.
• Children under 2 years of age: Do not use, consult a doctor.
• For external use only.
• Apply to affected area with mild soap and warm water. Rub in thoroughly, gently, dry by patting or blotting with a towel. Use as directed. Do not use on the face or other sensitive areas unless directed by a doctor.
• Children under 12 years of age: Consult a doctor.

Other information
• Storage temperature: Store at controlled room temperature (20° to 25°C (68° to 77°F)).
• Keep away from heat and moisture. Do not use if the seal is broken or the container is damaged.
• Contains 1% Hydrocortisone.
• Contains 1% Aloe Vera.
• Contains 1% Aloe Vera.
• Contains 1% Aloe Vera.

Caution
• Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
• Stop use and ask a doctor if:
• symptoms last for more than 7 days; • the condition gets worse; • symptoms start up and occur again in a few days; • red, white, or yellow discharge occurs; consult doctor for help.
• Do not use more than directed unless directed by a doctor.
• Do not puncture this product through the seal by using fingers or any mechanical device or applicator.

Contains
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AVEDANA HYDROCORTISONE CREAM WITH ALOE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43749-621
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43749-621-01	1 in 1 CARTON	08/27/2021	
1	NDC:43749-621-03	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			

OTC monograph not final	part348	08/27/2021	
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Labeler - Unipack LLC (009248480)

Registrant - Unipack LLC (009248480)

Establishment

Name	Address	ID/FEI	Business Operations
Unipack LLC		009248480	manufacture(43749-621)

Revised: 1/2023

Unipack LLC