# 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.

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### 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 gential, 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 solft 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.

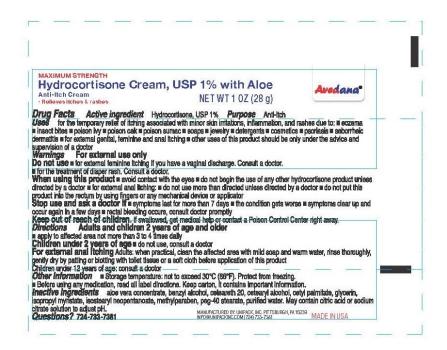
### **Inactive ingredients**

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?

Call 724-733-7381

Avedana ® Hydrocortisone Cream with Aloe | 1oz Tube label



Avedana® Hydrocortisone Cream with Aloe | 1oz Carton label



## **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





#### Relieves itches & rashes.

#### MAXIMUM STRENGTH

### Hydrocortisone Cream, USP 1% with Aloe

Anti-Itch Cream

Avedana®

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

#### NET W T 1 OZ (28 g)

#This product is not affiliated with, manufactured by, or produced by Chattern, the owners of Contizone \*10 €.

Distributed By: Unipack, Inc. Prittsburgh, PA 15239. Info@unipackinc.com (724)733-7381



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Drug Facts

### **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	<b>Basis of Strength</b>	Strength

HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ) HYDROCORTISONE 10 mg in 1 g

### **Inactive Ingredients**

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Ingredient Name	Strength	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
CETYL PALMITATE (UNII: 5ZA2S6B08X)		
METHYLPARABEN (UNII: A218C7H19T)		
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)		
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)		

#### Product Characteristics

PEG-40 STEARATE (UNII: ECU18C66Q7)

Floudet Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### **Packaging**

# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:43749-621-	1 in 1 CARTON	08/27/2021	
NDC:43749-621-	28 g in 1 TUBE; Type 0: Not a Combination Product		

# **Marketing Information**

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

final	part348	08/27/2021	

# 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