AVEDANA HYDROCORTISONE CREAM WITH ALOE- hydrocortisone cream Unipack LLC

Avedana ® Hydrocortisone Cream with Aloe

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 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

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 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.

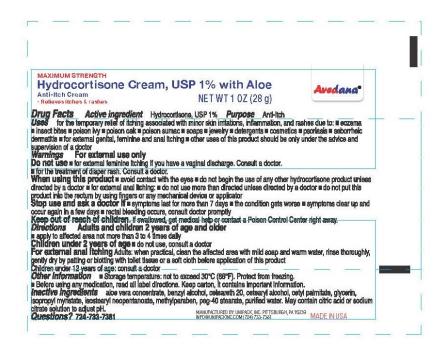
Inactive ingredients

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?

724-733-7381

Avedana ® Hydrocortisone Cream with Aloe | 1oz Tube label



Avedana ® Hydrocortisone Cream with Aloe | 1oz Carton label



AVEDANA HYDROCORTISONE CREAM WITH ALOE

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43749-620
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10.2 mg in 1 g		

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
CETYL PALMITATE (UNII: 5ZA2S6B08X)		
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)		
METHYLPARABEN (UNII: A218C7H19T)		
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)		
PEG-40 STEARATE (UNII: ECU18C66Q7)		
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:43749-620- 02	1 in 1 CARTON	04/07/2016		
1	NDC:43749-620- 01	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 Drug	M017	04/07/2016	

Registrant - Unipack LLC (116015769)

Establishment				
Name	Address	ID/FEI	Business Operations	
Unipack LLC		009248480	manufacture(43749-620)	

Revised: 3/2025 Unipack LLC