

AFASSCO 1% HYDROCORTISONE- hydrocortisone ointment

Afasco 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.

1% Hydrocortisone Cream

Drug Facts

Hydrocortisone Cream 1%

Active Ingredients (In Each Gram)

Hydrocortisone 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, detergents, cosmetics, jewelry, seborrheic dermatitis, and psoriasis scrapes
- 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

Consult a doctor:

- before use if you have a vaginal discharge (for external feminine itching)
- for external itching, do not exceed the recommended daily dosage or if bleeding occurs
- if condition worsens or if symptoms persist for more than 7 days or clear up and occur again in a few days
- ask a doctor before use if you are using any other hydrocortisone product

When using this product:

- avoid contact with eyes
- do not put this product into rectum by using fingers or any mechanical device or applicator

Do not use:

- with any other Hydrocortisone product unless you have consulted a doctor
- **KEEP OUT OF REACH OF CHILDREN.** If swallowed contact a Poison Control center right away.

Directions

- For 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
- Adults for external anal itching when practical, cleanse the area with mild soap and warm water and rinse thoroughly or by patting or blotting with an appropriate cleansing pad
- Gently dry by patting or blotting with toilet tissue or soft cloth before application of this product
- Children under 12 years of age; for external itching, consult a doctor

Other Information:

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aplique el producto.

**1% ANTI-ITCH ANALGESIC • FOR THE
TEMPORARY RELIEF OF MINOR SKIN IRRITATIONS**

No. 608 25 ct.

Afassco®

The First Choice in First Aid

Manufactured for Afassco, Inc. Minden, NV 89423

6 70254 60812 5

↓25 ct. Box↓



↓6 ct. Box↓



↓ Unit Dose Package Label ↓

Afassco®

The First Choice in First Aid

1% Hydrocortisone

Cream

Manufactured for Afassco

Minden, NV 89423

1gm (1/32 oz)

Made in China



1% Hydrocortisone Cream

Manufactured for
Afassco
Minden, NV 89423

1gm (1/32 oz)

Drug Facts

Active Ingredient	Purpose
Hydrocortisone 1%...	Anti-itch

Uses temporarily relieves itching associated with minor skin irritations, inflammation and rashes due to: eczema, insect bites, poison ivy, oak or sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis and more

Warnings
For external use only ▶

Drug Facts (continued)

Do not use ■ in or near the eyes ■ for diaper rash; ask a doctor

Ask a doctor before use if you are using any other hydrocortisone product

Stop use and ask a doctor if ■ condition worsens or if symptoms persist for more than 7 days ■ symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children If ingested, contact a Poison Control Center right away.

Directions ■ apply to affected area not more than 3 to 4 times daily ■ children under 2 years, do not use; ask a doctor

Other Information
protect from Excessive Heat (40°C/104°F)

Inactive Ingredients
Water, Cetearyl Alcohol, Glycerin, Ceteareth-20, Isopropyl Myristate, EDTA-2NA, Phenoxyethanol, Tocopheryl Acetate, Aloe Barbadosensis Leaf Juice

Made in China

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AFASSCO 1% HYDROCORTISONE

hydrocortisone ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51532-4608
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0 X7BPJ) (HYDROCORTISONE - UNII:WI4X0 X7BPJ)	HYDROCORTISONE	0.01 g in 1g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51532-4608-1	25 in 1 BOX	12/07/2018	
1		1 g in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:51532-4608-2	6 in 1 BOX	12/07/2018	
2		1 g in 1 POUCH; 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	12/07/2018	

Labeler - Afassco Inc. (609982723)**Registrant** - Afassco Inc. (956159800)