

**AFASSCO 1% HYDROCORTISONE- hydrocortisone ointment**  
**Afassco 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.*

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**1% Hydrocortisone Cream**

**Drug Facts**

**Hydrocortisone Cream 1%**

**Active Ingredients (In Each Gram)**

Hydrocortisone 1%

**Purpose**

Anti-itch

**Uses:**

- for the temporary temporarily 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 contacty with eyes
- do not put this produce 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:**

- Store at controlled room temperature 15° to 30° C (59° to 86° F)
- Tamper evident. Do not use if packet is torn, cut, or opened.
- Avoid excessive heat and humidity

#### ***Inactive Ingredients***

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

#### **Principal Display Panel**

**Afassco**  ®

**The First Choice  
in First Aid**

***MAXIMUM STRENGTH  
HYDROCORTISONE  
PLUS MOISTURIZING ALOE***

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

**No. 608 25 ct.**

**Afassco**  ®

**The First Choice in First Aid**

**REMOVE TOP FOR EASY ACCESS**

**Compare To**

**Hydrocortisone**

***MAXIMUM STRENGTH  
HYDROCORTISONE***

**1% ANTI-ITCH ANALGESIC • FOR THE**



**TEMPORARY RELIEF OF MINOR SKIN IRRITATIONS**

**No. 608**

**25 ct.**

**Afassco**  <sup>®</sup>

**The First Choice in First Aid**

***MAXIMUM STRENGTH  
HYDROCORTISONE***

1% Crema de Fydrocortisona

instrucciones: Para Adultos y ninos

2 anos y mas viejo. Los ninos bajo

2 anos, consultan un medico para

picar anal externo. Limpia el areaa

afectada con jabon y aclarado

aplique el producto.

**1% ANTI-ITCH ANALGESIC • FOR THE**

**TEMPORARY RELIEF OF MINOR SKIN IRRITATIONS**

**No. 608**

**25 ct.**

**Afassco**  <sup>®</sup>

**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

**Afassco**  ®  
*The First Choice in First Aid*

**1% Hydrocortisone  
Cream**

Manufactured for  
**Afassco**  
Minden, NV 89423  
**1gm (1/32 oz)**

### **Drug Facts**

<b>Active Ingredient</b>	<b>Purpose</b>
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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 Barbadensis Leaf Juice

Made in China



# 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: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	0.01 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWJY)	
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)



