

**AFTATE HYDROCORTISONE CREAM- hydrocortisone cream cream**  
**Sabel Med 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.*

**Hydrocortisone Cream USP 1% 1 oz**

**Directions**

- Clean the affected area
- Apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily
- May be covered with a sterile bandage

**Inactive ingredients**

cetomacrogol 1000 ,cetostearyl alcohol, chlorocresol, edetate disodium, liquid paraffin, propylene glycol, purified water, sodium meta bisulphite, white soft paraffin

**Active ingredient**

Hydrocortisone 1%.....

**Keep out of reach of children.**

**If swallowed, get medical help or contact a Poison Control Center right away.**

1058  
i-Itch

**Purpose**

.....Anti-Itch

**Warnings**

**For external use only**

- Do not use ■ in the eyes ■ if you are allergic to any of the ingredients
- over large areas of the body ■ longer than 1 week unless directed by a doctor

- Ask a doctor before use in case of ■ deep puncture wounds ■ animal bites
- serious burns

- Stop use and ask a doctor if ■ condition persists or gets worse
- rash or other allergic reaction develops

**Uses**

- temporarily relieves itching associated with: ■ minor skin irritation
- inflammations and rashes due to: ■ eczema ■ psoriasis ■ insect bites
- poison ivy ■ detergents, jewelry and cosmetics

2 mm BG Area can be extend but after formation of the tube will come on back panel



Net wt 1oz. (28 g)

**Maximum Strength**  
**Hydrocortisone**  
**Cream USP 1%**

NDC 70356-201-01

**Stop the Itch**

**Anti-Itch** Used For: Rash / Eczema / Psoriasis / Redness / Inflammation / Other skin irritations

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredient</b>	<b>Purpose</b>	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Hydrocortisone 1%.....	Anti-Itch	<b>Directions</b>	
<b>Uses</b>		Clean the affected area	
temporarily relieves itching associated with: ■ minor skin irritation		Apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily ■ May be covered with a sterile bandage	
■ inflammations and rashes due to: ■ eczema ■ psoriasis ■ insect bites		<b>Other information</b>	
■ poison ivy ■ detergents, jewelry and cosmetics		store at 15°-30°C (59°-86°F) ■ avoid excessive heat and humidity	
<b>Warnings</b>		<b>Inactive ingredients</b> cetomacrogol 1000, cetostearyl alcohol, chlorocresol, edetate disodium, liquid paraffin, propylene glycol, purified water, sodium meta bisulphite, white soft paraffin	
For external use only		<b>Questions?</b> Call toll free 866.5Aftate or 888.523.8283	
Do not use ■ in the eyes ■ if you are allergic to any of the ingredients		Distributed by: Sabel Med LLC	
■ over large areas of the body ■ longer than 1 week unless directed by a doctor		Oldsmar, FL 34677	
Ask a doctor before use in case of ■ deep puncture wounds ■ animal bites		Aftate™ RetroBrands U.S.A. LLC 2016	
■ serious burns		Retain carton for important product information	
Stop use and ask a doctor if ■ condition persists or gets worse		Made in India	
■ rash or other allergic reaction develops		MH/DRUGS/KD-180	

5mm

1:  
1m  
8X3m

## AFTATE HYDROCORTISONE CREAM

hydrocortisone cream cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70356-201
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W14X0 X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MINERAL OIL (UNII: T5L8T28FGP)	
CETETH-20 (UNII: I835H2IHHX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CHLOROCRESOL (UNII: 36W53O7109)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
PETROLATUM (UNII: 4T6H12BN9U)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70356-201-01	28 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2016	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/01/2016	

**Labeler** - Sabel Med LLC (091476000)

Revised: 3/2016

Sabel Med LLC