

HYDROCORTISONE- hydrocortisone cream
Safetec of America, Inc.

61010-5800,Safetec First Aid 1% Hydrocortisone Cream

Drug Facts

Active ingredient

Hydrocortisone 1.0%

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, psoriasis and scrapes
- 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 the treatment of diaper rash
- in eyes
- for feminine itching
- if condition worsens or lasts more than 7 days, or clears up and occurs again within a few days
- with any other Hydrocortisone product unless you have consulted a doctor

KEEP OUT OF REACH OF CHILDREN.

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

Directions:

- for adults and children 2 years of age and older: apply to affected area 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 affected 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 a soft cloth before application of this product
- children under 12 years of age: for external anal itching, consult a doctor

Other information:

- store at room temperature (do not freeze)
- do not use any opened or torn packets

Inactive ingredients:

emulsifying wax, ethanol, methylparaben, mineral oil, paraffin, petrolatum, propylparaben, purified water, white wax

Questions or Comments? 1-800-456-7077

Manufactured by
SAFETEC OF AMERICA, Inc.
Buffalo, NY 14215 . 800-456-7077
www.safetec.com

PRINCIPAL DISPLAY PANEL**PRINCIPAL DISPLAY PANEL - 0.9g Pouch Label****Safetec****1% Hydrocortisone Cream™**

0.9 g (1/32 oz.)

Safetec of America, Inc.

Buffalo, NY 14215

800-456-7077



1% Hydrocortisone CreamTM

0.9 g (1/32 oz.)

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Buffalo, NY 14215
800-456-7077

Drug Facts

Active ingredient Purpose

Hydrocortisone 1.0%. . .Anti-itch

Uses For temporary relief of itching associated with minor skin irritations, inflammation, or rashes. Other uses of product should be only under the advice and supervision of a doctor.

Warnings

For external use only

Do not use ■ in eyes ■ for treatment of diaper rash ■ for feminine itching ▶

Drug Facts (continued)

Stop use, ask a doctor ■ if condition worsens or lasts more than 7 days, or clears up and occurs again within a few days ■ with use of other hydrocortisone products

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: ask a doctor

Inactive ingredients

emulsifying wax, ethanol, methylparaben, mineral oil, paraffin, petrolatum, propylparaben, purified water, white wax

PRINCIPAL DISPLAY PANEL - Box Label

NDC 61010-5800-2

Safetec

First Aid

1% Hydrocortisone Cream

For Temporary Relief of Itching Associated with Minor Skin Irritations, Inflammation, or Rashes

Reorder no. 53110

To reorder:

Call: 1-800-456-7077

Fax: 716-895-2969

Online: www.safetec.com



First Aid

1% Hydrocortisone Cream

For Temporary Relief of Itching Associated with Minor Skin Irritations, Inflammation, or Rashes

144 Packets
Each Packet Net. Wt. 0.9gm

Drug Facts

Active ingredient	Purpose
Hydrocortisone 1.0%	Anti-itch

Uses:

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NDC 61010-5800-2



First Aid

1% Hydrocortisone Cream

For Temporary Relief of Itching Associated with Minor Skin Irritations, Inflammation, or Rashes



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Fax: 716-895-2969
Online: www.safetec.com

144 Packets
Each Packet Net. Wt. 0.9gm

PRINCIPAL DISPLAY PANEL - 10 Packet Box Label

Safetec®

FIRST AID

Hydrocortisone Cream

*1% Hydrocortisone for relief from itching,
inflammation, and rashes*

10 Packets

Each Packet Net Wt. 0.9g

Made in USA

Reorder no. 53108

10 packets
Each Packet Net. Wt. 0.9g



FIRST AID⁺ Hydrocortisone Cream

Drug Facts

Active Ingredient **Purpose**
Hydrocortisone 1.0% Anti-itch

Uses:

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Warnings

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FIRST AID⁺
Hydrocortisone Cream



FIRST AID⁺

Hydrocortisone Cream

1% Hydrocortisone for relief from itching,
inflammation, and rashes

10 Packets

Each Packet Net. Wt. 0.9g

Made in USA

Reorder No. 53108

FIRST AID⁺
Hydrocortisone Cream

HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61010-5800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
STEARETH-20 (UNII: L0Q8IK9E08)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61010-5800-3	25 in 1 BOX	12/15/2010	
1	NDC:61010-5800-1	0.9 g in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:61010-5800-2	144 in 1 BOX	12/15/2010	
2	NDC:61010-5800-1	0.9 g in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:61010-5800-4	10 in 1 BOX	04/01/2020	
3	NDC:61010-5800-1	0.9 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 Drug	M017	12/15/2010	

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	manufacture(61010-5800)

Revised: 2/2024

Safetec of America, Inc.