

1 HYDROCORTISONE MAXIMUM STRENGTH- hydrocortisone ointment

American Sales Company

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.

American Sales Company 1% Hydrocortisone Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
- eczema
- psoriasis
- poison ivy, oak, sumac
- insect bites
- detergents
- jewelry
- cosmetics
- soaps
- seborrheic dermatitis
- temporarily relieves external anal and genital itching
- other uses of this product should only be under the advice and supervision of a doctor

Warnings

For external use only

Do not use

- in the genital area if you have a vaginal discharge. Ask a doctor.
- for the treatment of diaper rash. Ask a doctor.

When using this product

- avoid contact with the eyes
- do not use more than directed unless told to do so by a doctor
- do not put directly into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens

- symptoms persist for more than 7 days or clear up and occur again within a few days, and do not begin use of any other hydrocortisone product unless you have asked a doctor
- rectal bleeding occurs

Keep out of reach of children.

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

Directions

- for itching of skin irritation, inflammation, and rashes:
- 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, ask a doctor
- for external anal and genital itching, adults:
- when practical, clean the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a soft cloth before applying
- apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

Other information

- store at 20°-25°C (68°-77°F)

Inactive ingredients

aloe barbadensis leaf juice, white petrolatum

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to the Active Ingredient in Cortizone•10®

MAXIMUM STRENGTH

1% HYDROCORTISONE

ANTI-ITCH OINTMENT

Relieves Itch Fast

Skin Irritation – Rashes- Insect bites – Eczema & Psoriasis – Inflammation & Redness

Water resistant formula helps seal in healing

NET WT 1 OZ (28 g)

Compare to the
Active Ingredient
in Cortizone 10®*

NDC 41520-201-64

CAREONE®

MAXIMUM STRENGTH

1% HYDROCORTISONE
ANTI-ITCH OINTMENT

Relieves Itch Fast
• Skin Irritation • Rashes • Insect bites
• Eczema & Psoriasis • Inflammation & Redness
Water resistant formula helps seal in healing

MAXIMUM STRENGTH

CAREONE®

1% HYDROCORTISONE
ANTI-ITCH OINTMENT

MAXIMUM STRENGTH

CAREONE®

1% HYDROCORTISONE
ANTI-ITCH OINTMENT

NET WT 1 OZ
(28g)

CODE AREA



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 - cosmetics ■ soaps ■ seborrheic dermatitis
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Drug Facts (continued)

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CODE AREA
: 4716 4 D4 CE



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hydrocortisone ointment

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:41520-201
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (HYDROCORTISONE)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF	
PETROLATUM	

Product Characteristics

Color	WHITE (clear)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-201-64	1 in 1 CARTON		
1		28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/17/2012	

Labeler - American Sales Company (809183973)

Revised: 10/2013

American Sales Company