

HYDROCORTISONE- hydrocortisone cream
Nantong Health & Beyond Hygienic Products 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.

Hydrocortisone

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- for the temporary relief of itching associated with minor irritations and rashes
- 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. Consult a doctor.

Stop use and ask a doctor if

- condition worsens or lasts more than 7 days, or clears up and occurs again within a few days.
- you begin use of any other hydrocortisone product
- bleeding occurs

Keep out of reach of children.

If swallowed contact a Poison Control Center right away.

Directions

- 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.

Inactive ingredients

Cetearyl alcohol, Ceteareth-20, Ethylhexylglycerin, Glycerin, Glycerol fatty acid ester, Mineral Oil, Petrolatum, Phenoxyethanol, Water

Package Labeling:

Hydrocortisone
Maximum Strength
Anti-Itch

KEEP > GOING
FIRST AID

NET WT 0.9 g

Manufactured for: KeepGoing
First Aid, Orlando, FL 32804
Made in China

| Drug Facts | |
|--|----------------|
| Active ingredient | Purpose |
| Hydrocortisone 1% | Anti-itch |
| Uses ■ for the temporary relief of itching associated with minor irritations and rashes ■ 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. Consult a doctor. | |
| Stop use and ask a doctor if ■ condition worsens or lasts more than 7 days, or clears up and occurs again within a few days. ■ you begin use of any other hydrocortisone product ■ bleeding occurs | |
| Keep out of reach of children. If swallowed contact a Poison Control Center right away. | |
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HYDROCORTISONE

hydrocortisone cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:43473-049 |
| 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 |
|--|----------|
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:43473-049-01 | 0.9 g in 1 PACKET; Type 0: Not a Combination Product | 05/08/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 05/08/2023 | |

Labeler - Nantong Health & Beyond Hygienic Products Inc. (421280161)

Revised: 5/2023

Nantong Health & Beyond Hygienic Products Inc.