

REGULAR STRENGTH HYDROCORTISONE CREAM- hydrocortisone cream cream

Walgreens

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.

Active Ingredient

Hydrocortisone, USP 0.5%

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, jewelry, detergents, cosmetics, psoriasis, seborrheic dermatitis, 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

Do not use

for external feminine itching if you have a vaginal discharge. Consult a doctor.

for the treatment of diaper rash. Consult a doctor.

When using this product

avoid contact with the eyes, do not begin the use of any other hydrocortisone product unless directed by a doctor, for external anal itching: do not use more than directed unless directed by a doctor, do not put this product into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

symptoms last for more than 7 days, the condition gets worse, symptoms clear up and occur again in a few days, rectal bleeding occurs, consult doctor promptly

Keep out of reach of children.

If swallowed, get medical help or 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, consult a doctor.

For external anal itching - Adults: when practical, clean the affected area with mild soap and warm

water, rinse thoroughly, gently dry by patting or blotting with toilet tissue or a soft cloth before applicaion of this product.

Children under 12 years of age: consult a doctor.

Other information

Storage temperature: not to exceed 30°C (86°F). Protect from freezing.

Before using any medication, read all label directions. Keep carton, it contains important information.

Inactive Ingredients

benzyl alcohol, cetareth 20, cetearyl alcohol, cetyl palmitate, glycerin, isopropyl myristate, isostearyl neopentanoate, methylparaben, peg-40 stearate, purified water. May contain citric acid or sodium citrate solution to adjust pH.

Carton Label

Walgreens

- Soothing relief for skin irritations, rashes, redness & inflammation

REGULAR STRENGTH

Relieves itches & rashes

Hydrocortisone Cream

HYDROCORTISONE 0.5% / ANTI-ITCH CREAM

Walgreens

NET WT 2 OZ (56 g)

† Walgreens Pharmacist Survey

DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015
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WIC 931428 W10611-0617-L



Health expertise
you rely on,
quality you trust.

RECOMMENDED
Walgreens
PHARMACIST

Drug Facts

Active ingredient: Hydrocortisone, USP 0.5%.

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 ■ rashes
- allergic dermatitis ■ contact dermatitis ■ diaper rash ■ hemorrhoids ■ insect bites ■ poison ivy ■ poison oak ■ poison sumac ■ rashes

Warnings:

- For external use only
- Do not use ■ For the treatment of diaper rash. Consult a doctor.
- When using this product ■ Do not touch the eyes ■ Do not touch the eyes ■ Do not touch the eyes
- Avoid contact with the eyes ■ Do not touch the eyes ■ Do not touch the eyes
- Do not use more than directed unless directed by a doctor
- Do not put this product into the rectum by using fingers or any mechanical device or applicator
- Stop use and ask a doctor if ■ Symptoms last for more than 7 days ■ The condition gets worse
- Symptoms clear up and occur again in a few days ■ Rash/bleeding occurs, consult doctor promptly
- Keep out of reach of children. If swallowed, get medical help or 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, consult a doctor
- For external anal itching ■ Do not use, consult a doctor
- Adults: When directed, clean the affected area with mild soap and warm water, then thoroughly, gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
- Children under 12 years of age: consult a doctor

Other information:

- Storage temperature: not to exceed 30°C (86°F). Protect from freezing.
- Before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredients: benzyl alcohol, carbomer 20, cetyl palmitate, glycerin, isopropyl myristate, isostearyl myristate, methylparaben, poly-40 stearate, purified water. May contain citric acid or sodium citrate solution to adjust pH.

Questions? 1-800-925-4733



• Soothing relief for skin irritations, rashes, redness & inflammation

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Relieves itches & rashes

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you rely on,
quality you trust.



Drug Facts

Active ingredient: Hydrocortisone, USP 0.5%.

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
- sunburn
- allergic dermatitis
- jewelry
- hemorrhoids

Warnings:

- For external use only.
- Do not use ■ For external hemorrhoids (itching if you have a vaginal discharge). Consult a doctor.
- When using this product:
- Avoid contact with the eyes
- Do not touch the use of any other hydrocortisone product unless directed by a doctor.
- For external anal itching:
- Do not use more than 7 days unless directed by a doctor.
- Do not put this product into the rectum by using fingers or any mechanical device or applicator.
- Stop use and ask a doctor if:
- Symptoms last for more than 7 days ■ The condition gets worse
- Symptoms clear up and occur again in a few days ■ Itching, burning, or 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, consult a doctor
- For external anal itching
- Adults: When directed, clean the affected area with mild soap and warm water, then thoroughly, gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.
- Children under 12 years of age: consult a doctor.

Other Information:

- Store at controlled room temperature, not to exceed 30°C (86°F). Protect from freezing.
- Before using any medication, read all label directions. Keep container tightly closed.

Questions? 1-800-925-4773

Contains: purified water. May contain citric acid or sodium citrate solution to adjust pH.

Inactive ingredients: benzyl alcohol, carbomer 20, cetyl palmitate, glycerin, isopropyl myristate, lauric acid, methylparaben, poly-4-vinylpyrrolidone, purified water.



REGULAR STRENGTH HYDROCORTISONE CREAM

hydrocortisone cream cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-0639 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------------------------|-------------------|-----------------|
| HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ) | HYDROCORTISONE | 0.51 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------------------------|------------------|
| WATER (UNII: 059QF0KO0R) | 79.79 g in 100 g |
| GLYCERIN (UNII: PDC6A3C0OX) | 1 g in 100 g |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS) | 7 g in 100 g |
| CETYL PALMITATE (UNII: 5ZA2S6B08X) | 4 g in 100 g |
| ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q) | 0.5 g in 100 g |
| METHYL PARABEN (UNII: A2I8C7HI9T) | 0.2 g in 100 g |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | 1.5 g in 100 g |
| PEG-40 STEARATE (UNII: ECU18C66Q7) | 0.5 g in 100 g |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | 1 g in 100 g |
| POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY) | 4 g in 100 g |

Product Characteristics

| | | | |
|----------|-------|--------------|--|
| Color | white | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------------------------------|----------------------|--------------------|
| 1 | NDC:0363-0639-03 | 1 in 1 CARTON | 06/07/2016 | |
| 1 | NDC:0363-0639-01 | 56 g in 1 TUBE; 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 | 06/07/2016 | |

Labeler - Walgreens (008965063)

| Establishment | | | |
|---------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Unipack, Inc. | | 009248480 | manufacture(0363-0639) |