HYDROCORTISONE - hydrocortisone acetate ointment Water-Jel Technologies

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.

1% Hydrocortisone Cream

Active ingredient

Hydrocortisone acetate (equivalent to Hydrocortisone 1%)

Purpose

Anti-itch cream

Uses

- for the temporary relief of itching associated with minor skin 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

When using this product

- avoid contact with eyes
- do not begin use of any other hydrocortisone product unless you've consulted a doctor

Stop use and ask a doctor if

- condition worsens
- symptoms persist more than 7 days
- condition clears up and occurs again within a few days

Keep out of the 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; do not use, consult a doctor

Other information

- clean the affected area
- store at room temperature
- tamper evident sealed packets
- do not use any opened or torn packets
- you may report a serious adverse reaction to this product to 800-275-3433

Inactive ingredients

cetyl alcohol, citric acid, diazolidinyl urea, edetate disodium, glycerin, glyceryl monostearate, methylparaben, mineral oil, polyethylene glycol, propylene glycol, propylparaben, purified water, stearic acid, trolamine

Questions?
800-275-3433
info@waterjel.com
www.waterjel.com

Principal Display Panel



Enter section text here

anti-itch cream ointment

| Product Information | | | |
|----------------------------|----------------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG LABEL | Item Code (Source) | NDC:59898-800 |
| Route of Administration | TOPICAL | DEA Schedule | |

| Active Ingredient/Active Moiety | | | | |
|---|------------------------|--------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| HYDROCORTISONE ACETATE (HYDROCORTISONE) | HYDROCORTISONE ACETATE | 1 g in 100 g | | |

| Inactive Ingredients | | | |
|-----------------------|----------|--|--|
| Ingredient Name | Strength | | |
| EDETATE DISODIUM | | | |
| LIGHT MINERAL OIL | | | |
| STEARIC ACID | | | |
| GLYCERYL MONOSTEARATE | | | |
| POLYETHYLENE GLYCOLS | | | |
| CETYL ALCOHOL | | | |
| TROLAMINE | | | |
| METHYLPARABEN | | | |
| PROPYLENE GLYCOL | | | |
| DIAZOLIDINYL UREA | | | |
| PROPYLPARABEN | | | |
| GLYCERIN | | | |
| WATER | | | |

| Packaging | | | | |
|-------------------|-------------------|-------------|----------------------|--------------------|
| # Item Cod | e Package | Description | Marketing Start Date | Marketing End Date |
| 1 NDC:59898-800-0 | 3 25 in 1 BOX, U | NIT-DOSE | | |
| 1 | 0.9 g in 1 PACE | KET | | |
| 2 NDC:59898-800-0 | 2 144 in 1 BOX, U | JNIT-DOSE | | |
| 2 | 0.9 g in 1 PACE | KET | | |
| 3 NDC:59898-800-0 | 1 1728 in 1 CART | ON | | |
| 3 | 0.9 g in 1 PACE | KET | | |
| 4 NDC:59898-800-3 | 6 0.9 g in 1 PACE | ŒТ | | |
| 5 NDC:59898-800-3 | 2 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 | 04/30/2010 | | |
| | | | | |

Labeler - Water-Jel Technologies (155522589)

| Establishment | | | |
|------------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Water-Jel Technologies | | 155522589 | manufacture(59898-800) |

Revised: 3/2013 Water-Jel Technologies