

## **HYDROCORTISONE - hydrocortisone acetate ointment**

### **North Safety Products**

*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**

(In each gram)

Hydrocortisone acetate (equivalent to Hydrocortisone 1%)

#### **Purpose**

Anti-itch cream

#### **Uses**

for the temporary relief of itching associated with minor skin irritations and rashes

#### **Warnings**

##### **For external use only**

##### **When using the product**

- avoid contact with eyes
- do not begin use of any other hydrocortisone product unless you have consulted a doctor
- do not use for the treatment of diaper rash

##### **Stop use and ask a doctor if**

- the condition gets worse
- condition persists for more than 7 days
- condition clears up and recurs within a few days

##### **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 and older:
- clean the affected area
- apply to the area not more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

#### **Other information**

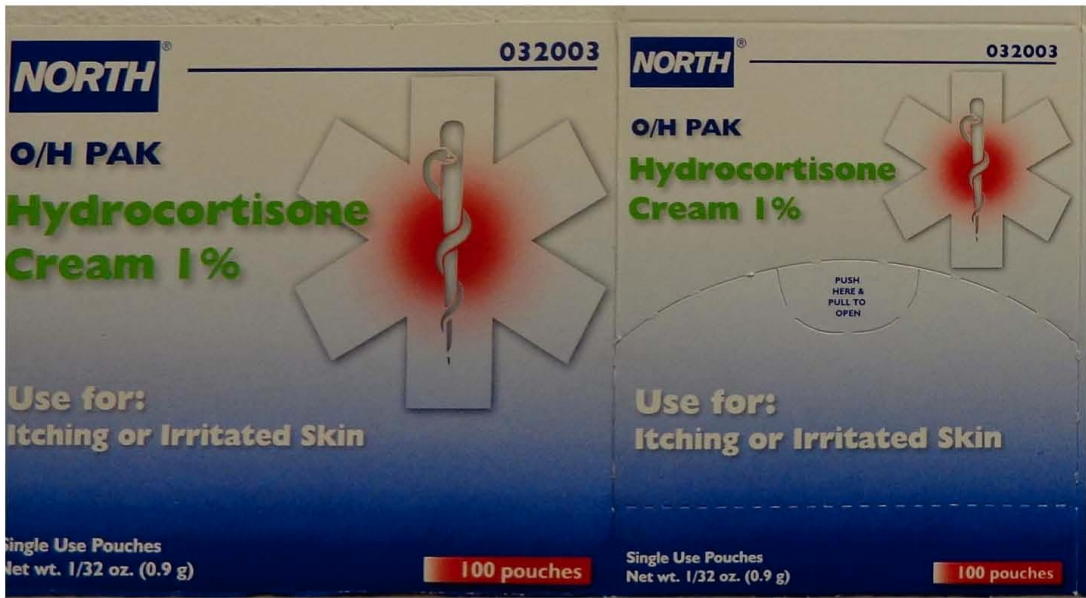
- store at room temperature
- tamper evident sealed packets
- do not use any opened or torn packets

**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

1-800-430-4110

**Principal Display Panel**



**HYDROCORTISONE**

anti-itch cream ointment

**Product Information**

|                                |                      |                           |               |
|--------------------------------|----------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG LABEL | <b>Item Code (Source)</b> | NDC:0498-0800 |
| <b>Route of Administration</b> | TOPICAL              | <b>DEA Schedule</b>       |               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>                  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| HYDROCORTISONE ACETATE (HYDROCORTISONE) | HYDROCORTISONE ACETATE   | 1 g in 100 g    |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|-------------------------|-----------------|
| EDETATE DISODIUM        |                 |
| LIGHT MINERAL OIL       |                 |
| STEARIC ACID            |                 |
| GLYCERYL MONOSTEARATE   |                 |
| POLYETHYLENE GLYCOLS    |                 |
| CETYL ALCOHOL           |                 |
| TROLAMINE               |                 |
| METHYLPARABEN           |                 |
| PROPYLENE GLYCOL        |                 |
| DIAZOLIDINYL UREA       |                 |
| PROPYLPARABEN           |                 |
| GLYCERIN                |                 |
| WATER                   |                 |
| CITRIC ACID MONOHYDRATE |                 |

**Packaging**

| # | <b>Item Code</b> | <b>Package Description</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---|------------------|----------------------------|-----------------------------|---------------------------|
| 1 | NDC:0498-0800-03 | 25 in 1 BOX, UNIT-DOSE     |                             |                           |
| 1 |                  | 0.9 g in 1 PACKET          |                             |                           |
| 2 | NDC:0498-0800-02 | 144 in 1 BOX, UNIT-DOSE    |                             |                           |
| 2 |                  | 0.9 g in 1 PACKET          |                             |                           |
| 3 | NDC:0498-0800-01 | 1728 in 1 CARTON           |                             |                           |
| 3 |                  | 0.9 g in 1 PACKET          |                             |                           |
| 4 | NDC:0498-0800-32 | 20 in 1 BOX, UNIT-DOSE     |                             |                           |
| 4 |                  | 0.9 g in 1 PACKET          |                             |                           |
| 5 | NDC:0498-0800-33 | 100 in 1 BOX, UNIT-DOSE    |                             |                           |
| 5 |                  | 0.9 g in 1 PACKET          |                             |                           |
| 6 | NDC:0498-0800-34 | 10 in 1 BOX, UNIT-DOSE     |                             |                           |
| 6 |                  | 0.9 g in 1 PACKET          |                             |                           |
| 7 | NDC:0498-0800-35 | 0.9 g in 1 PACKET          |                             |                           |

## Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348                                  | 03/06/2013           |                    |

**Labeler** - North Safety Products (019777263)

## Establishment

| Name                  | Address | ID/FEI    | Business Operations    |
|-----------------------|---------|-----------|------------------------|
| North Safety Products |         | 019777263 | manufacture(0498-0800) |

## Establishment

| Name                   | Address | ID/FEI    | Business Operations    |
|------------------------|---------|-----------|------------------------|
| Water-Jel Technologies |         | 155522589 | manufacture(0498-0800) |

Revised: 3/2013

North Safety Products