HYDROCORTISONE ACETATE - hydrocortisone acetate ointment
Kinray 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.

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**Hydrocortisone**

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocortisone Acetate 1%</td>
<td>Antipruritic (anti-itch)</td>
</tr>
</tbody>
</table>

**Warnings:**

For external use only

**Purpose**

Hydrocortisone is for temporary relief of;

- minor skin irritations
- Itching and rashes due to;
- eczema
- insect bites
- poison ivy
- poison oak
- poison sumac
- soaps
- detergents
- cosmetics
- jewelry

and for external itching of;

- genital
- feminine and
- anal itching

**Indications and Usage**

- in the eyes
- longer than 1 week unless directed by a physician
- for diaper rash
- if you have vaginal discharge
- more than the recommended daily dosage unless directed by a doctor
- in the rectum bu using fingers or any other mechanical device or applicator
- For temporary relief of minor skin irritations and external itching.

**Stop use and ask a physician if:**

- the condition persists or gets worse
- symptoms clear up and occur again within a few days
- you are pregnant or breast feeding
Keep out of reach of children
- If swallowed, get medical help or contact a Poison Control Center right away.

Dosage and Administration
Adults and children over 2 years of age
- Apply evenly to affected area no more than 3 or 4 times daily.

Children under 2 years of age
- Do not use
- Consult a physician

Adults
- When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly
- Gently dry, patting and blotting with bathroom tissue or soft cloth before applying
- Apply externally to the area up to 6 times daily or after each bowel movement

Other information:
- Store at 20 deg - 25 deg C (68 deg - 77 deg F)
- Avoid excessive heat and humidity

Inactive ingredients:
Liquid Paraffin, White Soft Paraffin, Sorbitan Sesquioleate

Principal Display Panel
Hydrocortisone
Hydrocortisone.jpg
### HYDROCORTISONE ACETATE
hydrocortisone acetate ointment

#### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
<td>NDC:63777-247</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>TOPICAL</td>
</tr>
</tbody>
</table>

#### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WH4X0X7BPJ)</td>
<td>HYDROCORTISONE ACETATE</td>
<td>1 g in 100 g</td>
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### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tbody>
<tr>
<td>PARAFFIN (UNII: B00E3H2ZE)</td>
<td></td>
</tr>
<tr>
<td>LIGHT MINERAL OIL (UNII: N6K5787QVP)</td>
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</tr>
<tr>
<td>SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)</td>
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</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<td>NDC:63777-247-01</td>
<td>28.4 g in 1 TUBE; Type 0: Not a Combination Product</td>
<td>09/06/2011</td>
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### Marketing Information

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<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
<td>OTC monograph not final</td>
<td>part348</td>
<td>09/06/2011</td>
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### Labeler

Labeler - Kinray Inc. (012574513)

### Registrant

Registrant - Dynarex Corporation (008124539)

Revised: 6/2017

Kinray Inc.