**HYDROCORTISONE - hydrocortisone liquid**
**CVS Pharmacy**

*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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**drug facts**

**Active ingredient** **Purpose**

Hydrocortisone 1%.....External analgesic

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Hydrocortisone 1%.....External analgesic

**Uses** Temporarily relieves itching associated with minor skin irritation and rashes due to saborrheic dermatitis and psoriasis. Other uses of this product should be only used under the advice and supervision of a doctor.

**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: apply to affected areas one to four times daily
- children under 2 years of age, do not use, consult a doctor

**Warnings**

**For external use only.**

**When using this product**

- do not get into eyes. If contact occurs, rinse eyes thoroughly with water. If irritation persists, consult a doctor.

**Stop use of this product and do not begin use of any other hydrocortisone product if**

- condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days, unless you have consulted a doctor.

**Keep out of reach of children.** If swallowed, get medical

help or contact a Poison Control Center right away.

**Flammable,** Keep away from fire or flame.

**Directions**

- adults and children 2 years and older: apply to affected areas one to four times daily

- children under 2 years of age, do not use, consult a doctor

**Inactive Ingredients** SD Alcohol 40-B, water, propylene glycol, menthol, tocopheryl acetate, aloe barbadensis leaf juice, meialeuce alternilolia (tea tree) leaf oil, disodium EDTA


**HYDROCORTISONE**

hydrocortisone liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:59779-318 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **HYDROCORTISONE** (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ) | HYDROCORTISONE | 10 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **ALCOHOL** (UNII: 3K9958V90M) | |
| **MENTHOL** (UNII: L7T10EIP3A) | |
| **TEA TREE OIL** (UNII: VIF565UC2G) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **ALPHA-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:59779-318-03 | 1 in 1 CARTON | | |
| **1** | | 44 mL in 1 BOTTLE, DISPENSING | | |

| Marketing Information | | | |
|---|---|---|---|
| **Marketing Category** | **Application Number or Monograph Citation** | **Marketing Start Date** | **Marketing End Date** |
| OTC monograph final | part348 | 07/16/2010 | |

**Labeler -** CVS Pharmacy (062312574)

**Registrant -** Pharma Pac, LLC (140807475)

| Establishment | | | |
|---|---|---|---|
| **Name** | **Address** | **ID/FEI** | **Business Operations** |
| Pharma Pac, LLC | | 140807475 | manufacture |

Revised: 7/2010 CVS Pharmacy