**HYDROCORTISONE ACETATE- hydrocortisone acetate suppository**
**Marlex Pharmaceuticals, Inc.**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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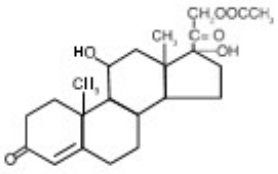
**Hydrocortisone Acetate Suppositories**
**Rx Only**

## DESCRIPTION

Each Hydrocortisone Acetate Suppository for rectal administration contains hydrocortisone acetate USP in a hydrogenated palm kernel oil base.

Hydrocortisone acetate is a corticosteroid. The molecular weight of hydrocortisone acetate is 404.50. Chemically, hydrocortisone acetate is pregn-4-ene-3, 20 dione, 21-(acetyloxy)-11, 17-dihydroxy-, (11β)- with an empirical formula of C23 H32O6 and the following structural formula:



## CLINICAL PHARMACOLOGY

In normal subjects, about 26 percent of hydrocortisone acetate is absorbed when the hydrocortisone acetate suppository is applied to the rectum. Absorption of hydrocortisone acetate may vary across abraded or inflamed surfaces.

Topical steroids are primarily effective because of their anti-inflammatory, antipruritic and vasoconstrictive action.

## INDICATIONS AND USAGE

Hydrocortisone Acetate Suppositories are indicated for use in inflamed hemorrhoids, post irradiation (factitial) proctitis, as an adjunct in the treatment of chronic ulcerative colitis, cryptitis, other inflammatory conditions of the anorectum, and pruritus ani.

## CONTRAINDICATIONS

Hydrocortisone Acetate Suppositories are contraindicated in those patients with a history of hypersensitivity to any of the components.

## PRECAUTIONS

Do not use unless adequate proctologic examination is made.

If irritation develops, the product should be discontinued, and appropriate therapy instituted.

In the presence of an infection, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, Hydrocortisone Acetate Suppositories should be discontinued until the infection has been adequately controlled.

### Carcinogenesis

No long-term studies in animals have been performed to evaluate the carcinogenic potential of corticosteroid suppositories.

## PREGNANCY CATEGORY C

In laboratory animals, topical steroids have been associated with an increase in the incidence of fetal abnormalities when gestating females have been exposed to rather low dosage levels. There are no adequate and well-controlled studies in pregnant women.

Hydrocortisone acetate suppositories should only be used during pregnancy if the potential benefit justifies the risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from hydrocortisone acetate suppositories, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

## ADVERSE REACTIONS

The following local adverse reactions have been reported with Hydrocortisone Acetate Suppositories: burning, itching, irritation, dryness, folliculitis, hypopigmentation, allergic contact dermatitis, and secondary infection.

**To report SUSPECTED ADVERSE REACTIONS, contact Marlex Pharmaceuticals at 1-888-582-1953 or drugsafety@marlexpharm.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

## DRUG ABUSE AND DEPENDENCE

Drug abuse and dependence have not been reported in patients treated with Hydrocortisone Acetate Suppositories.

## DOSAGE AND ADMINISTRATION

For rectal administration: Insert one suppository in the rectum twice daily, morning and night for two weeks, in nonspecific proctitis.In more severe cases, one suppository

three times a day or two suppositories twice daily. In factitial proctitis, the recommended duration of therapy is six to eight weeks or less, according to the response of the individual case.

Detach and hold one suppository upright(point upward). Separate tabs at top opening and pull downward to almost the full length of the suppository. Carefully remove the suppository, avoiding excessive handling, which is designed to melt at body temperature. Insert suppository into the rectum, pointed end first, with gentle pressure.

## HOW SUPPLIED

25mg (12 count) NDC 10135-0751-12

25mg (24 count) NDC 10135-0751-24

**Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Store away from heat. Protect from freezing.**

Manufactured for/ Distributed by:

Marlex Pharmaceuticals, Inc.

New Castle, DE 19720

Rev. 07/22 ID

## PRINCIPAL DISPLAY PANEL - 25 mg Suppository Carton

NDC 10135-0751-12

Rx Only

Hydrocortisone Acetate
Suppositories

25 mg

FOR RECTAL USE ONLY

12 Suppositories


**PRINCIPAL DISPLAY PANEL - 25 mg Suppository Carton**

NDC 10135-0751-24

Rx Only

Hydrocortisone Acetate
Suppositories

25 mg

FOR RECTAL USE ONLY

24 Suppositories


# HYDROCORTISONE ACETATE

hydrocortisone acetate suppository

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:10135-751 |
| **Route of Administration** | RECTAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **HYDROCORTISONE ACETATE** (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ) | HYDROCORTISONE ACETATE | 25 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **HYDROGENATED PALM OIL** (UNII: 257THB963H) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white ((White to Off-White)) | **Score** | |
| **Shape** | BULLET | **Size** | |
| **Flavor** | | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:10135-751-12 | 12 in 1 CARTON; Type 0: Not a Combination Product | 08/01/2022 | |
| **2** | NDC:10135-751-24 | 24 in 1 CARTON; Type 0: Not a Combination Product | 08/01/2022 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 08/01/2022 | |

## Labeler - Marlex Pharmaceuticals, Inc. (782540215)

Revised: 10/2024 Marlex Pharmaceuticals, Inc.