Hydrocortisone Acetate Suppositories 25 mg For Rectal Administration Rx Only

DESCRIPTION
Each Hydrocortisone Acetate 25 mg Suppository contains 25 mg hydrocortisone acetate in a hydrogenated vegetable oil base. Hydrocortisone acetate is a corticosteroid. Chemically, hydrocortisone acetate is a pregn-4-ene-3, 20-dione, 21-(acetyloxy)-11,17- dihydroxy (11β)- with the following structural formula:

\[
\text{C}_{23}\text{H}_{32}\text{O}_6 \\
\text{MW } 404.50
\]

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, anti-pruritic and vasoconstrictive action.

INDICATIONS AND USAGE
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 pruritis 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, the hydrocortisone acetate should be
discontinued until the infection has been adequately controlled.

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

INFORMATION FOR PATIENTS
Staining of fabric may occur with use of the suppository. Precautionary measures are recommended.

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, and 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 corticosteroid suppositories: burning, itching, irritation, dryness, folliculitis, hypopigmentation, allergic contact dermatitis and secondary infection.

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

OVERDOSAGE
If signs and symptoms of systemic overdosage occur, discontinue use.

DOSAGE AND ADMINISTRATION
Usual dosage: One suppository in the rectum morning and night for two weeks, in nonspecific proctitis. In more severe cases, one suppository three times daily; or two suppositories twice daily. In factitial proctitis, recommended therapy is six to eight weeks or less, according to response.

OPENING INSTRUCTIONS
Avoid excessive handling of the suppository, it is designed to melt at body temperature.
1. Detach one (1) suppository slowly from the strip of suppositories.
2. Separate tabs at top opening and pull downward slowly.
3. Continue pulling downward slowly to almost the full length of the suppository.
4. Gently remove the suppository from the package.
5. Insert suppository into the rectum, pointed end first, with gentle pressure.
HOW SUPPLIED

Hydrocortisone Acetate Suppositories are white, torpedo shaped, with one end tapered. Package of 12 suppositories NDC 43199-021-12 and package of 24 suppositories NDC 43199-021-24.


Rx Only.

Distributed by:
County Line Pharmaceuticals, LLC
Brookfield, WI 53005

For Inquiries Call:
1-866-207-5636

PI-CLP021B
6/11

PRINCIPAL DISPLAY PANEL - CARTON
Hydrocortisone Acetate Suppositories 25 mg

12 Suppositories

TAMPER EVIDENT: DO NOT USE IF FILM IS TORN OR BROKEN

Dosage and Administration: Read package insert for complete information before use.

Directions for Use: Avoid excessive handling of the suppository, it is designed to melt at body temperature. 1. Detach one (1) suppository slowly from the strip of suppositories. 2. Separate tabs at top opening and pull downward slowly. 3. Continue pulling downward slowly to almost the full length of the suppository. 4. Gently remove the suppository from the package. 5. Insert suppository into the rectum, pinched end first, with gentle pressure.

NOTE: Staining of fabric may occur with use of the suppository. Precautionary measures are recommended.

Store at 20°–25°C (68°–77°F) See USP Controlled Room Temperature. Store away from heat. Protect from freezing.

See end flap for expiration date and lot.

Manufactured for: County Line Pharmaceuticals, LLC

Hydrocortisone Acetate Suppositories 25 mg

12 Suppositories

TAMPER EVIDENT: DO NOT USE IF FILM IS TORN OR BROKEN
<table>
<thead>
<tr>
<th>HYDROCORTISONE ACETATE</th>
<th>25 mg SUPPOSITORY</th>
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<tr>
<td>Mfd for: County Line Pharmaceuticals, LLC Brookfield, WI 53005</td>
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Mfd for: County Line Pharmaceuticals, LLC Brookfield, WI 53005
# HYDROCORTISONE ACETATE
hydrocortisone acetate suppository

## Product Information

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<th>Product Type</th>
<th>Item Code (Source)</th>
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<tr>
<td>RECTAL</td>
<td>DEA Schedule</td>
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## Route of Administration

- RECTAL

## DEA Schedule

- 

## Active Ingredient/Active Moiety

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<th>Ingredient Name</th>
<th>Basis of Strength</th>
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## Product Characteristics

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## Marketing Information

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## Labeler

- County Line Pharmaceuticals, LLC (015585278)

## Registrant

- County Line Pharmaceuticals, LLC (015585278)

## Establishment

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<th>Name</th>
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<td>Bio-Pharm, Inc.</td>
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Revised: 5/2012