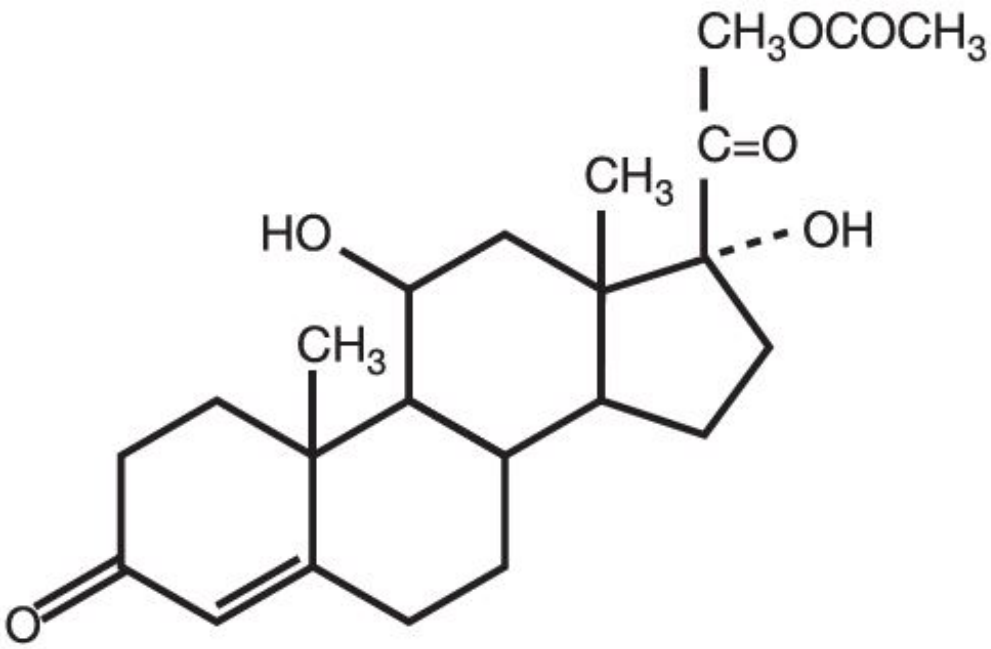
HYDROCORTISONE ACETATE- hydrocortisone acetate suppository
RPK Pharmaceuticals, Inc.

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.

Hydrocortisone Acetate Suppositories, 25 mg
For Rectal Administration
Rx only

DESCRIPTION

Hydrocortisone acetate is a corticosteroid designed chemically as pregn-4-ene-3, 20-dione, 21-(acetyloxy)-11, 17-dihydroxy-(11ß) with the following structural formula:



Each suppository for rectal administration contains hydrocortisone acetate, USP 25 mg in a specially blended hydrogenated vegetable base.

CLINICAL PHARMACOLOGY:

In normal subjects, about 26% 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:

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 anorectum, and pruritus ani.

CONTRAINDICATIONS:

Hydrocortisone acetate suppositories are contraindicated in those patients having a history of hypersensitivity to hydrocortisone acetate or any of the components.

PRECAUTIONS:

Do not use hydrocortisone acetate suppositories 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 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 of 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 hydrocortisone acetate suppositories; burning, itching, irritation, dryness, folliculitis, hypopigmentation, allergic contact dermatitis, secondary infection.

To report an adverse event, please contact Cameron Pharmaceuticals, LLC at 1-888-767-7913.

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:

FOR RECTAL ADMINISTRATION. Detach one suppository from strip of suppositories. Hold suppository upright and carefully separate tabs at top opening and pull downward from the pointed end to expose the suppository. Remove the suppository from the pocket. Avoid excessive handling of suppository which is designed to melt at body temperature. Insert one suppository rectally, pointed end first. 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.

HOW SUPPLIED:

Product: 53002-3440

NDC: 53002-3440-1 6 SUPPOSITORY in a BOX

NDC: 53002-3440-2 12 SUPPOSITORY in a BOX

STORAGE:

Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]. Excursions permitted to 15°-30°C (59°-86°F). Store away from heat. Protect from freezing. Avoid contact with eyes.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

PHARMACIST:

This product is not an Orange Book rated product, therefore all prescriptions using this product shall be subject to state and federal statutes as applicable. This product has not been subjected to FDA therapeutic or other equivalency testing. There are no claims of bioequivalence or therapeutic equivalence. Each person recommending a prescription substitution using this product shall make such recommendation based on his/her

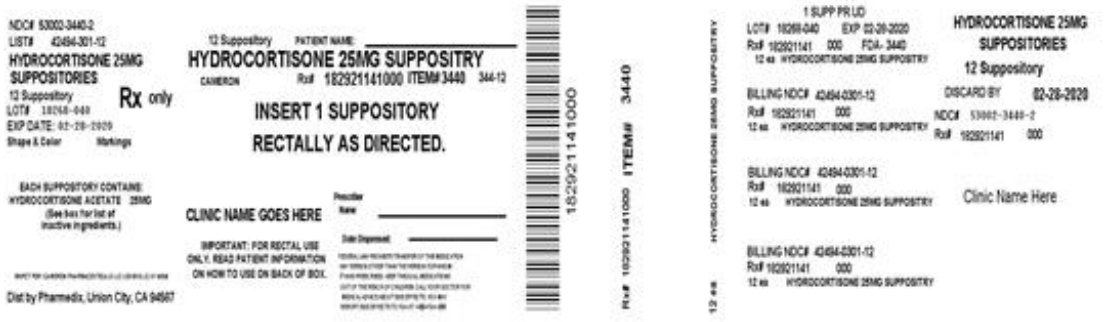
professional knowledge and opinion, upon evaluating the active ingredients, inactive ingredients, excipients and chemical information contained within the enclosed prescribing information.

Rx Only

Manufactured for:
Cameron Pharmaceuticals, LLC
Louisville, KY 40245

Rev. 07/16

Hydrocortisone 25mg Suppositories



HYDROCORTISONE ACETATE

hydrocortisone acetate suppository

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53002-3440(NDC:42494-301)
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**
C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53002-3440-2	12 in 1 BOX; Type 0: Not a Combination Product	10/01/2018	
2	NDC:53002-3440-1	6 in 1 BOX; Type 0: Not a Combination Product	10/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		05/01/2017	

Labeler - RPK Pharmaceuticals, Inc. (147096275)

Establishment

Name	Address	ID/FEI	Business Operations
RPK Pharmaceuticals, Inc.		147096275	RELABEL(53002-3440)

Revised: 6/2023 RPK Pharmaceuticals, Inc.