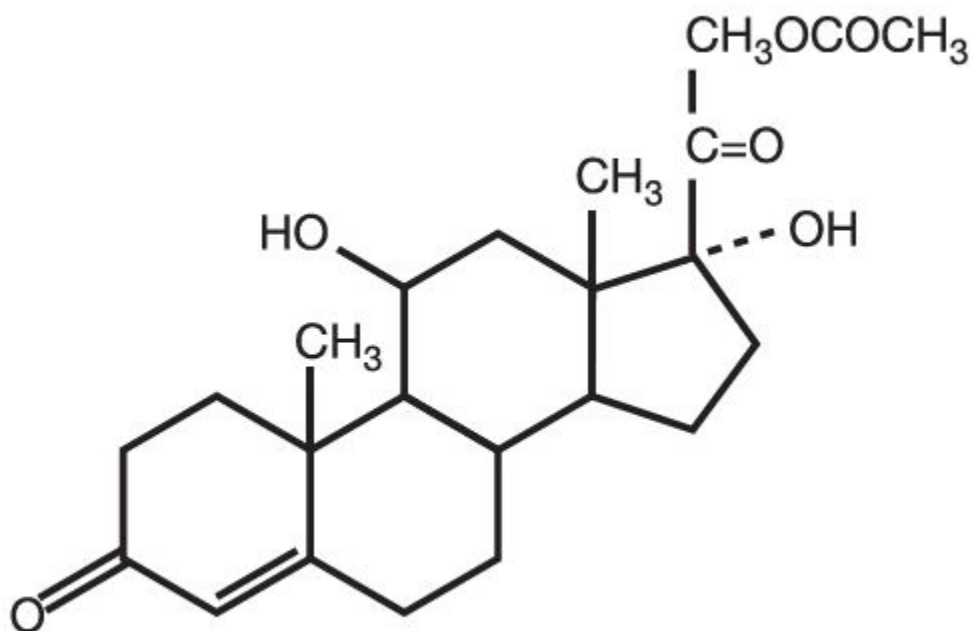


**Hydrocortisone Acetate Suppositories, 25 mg
For Rectal Administration
Rx only**

DESCRIPTION

Hydrocortisone acetate is a corticosteroid designed chemically as pregn-4-ene-3, 20-dione, 21-(acetyloxy)-11, 17-dihydroxy-(11 β) 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 (factual) 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:

Hydrocortisone acetate suppositories 25mg are off-white, smooth surfaced and bullet shaped with one pointed end.

Box of 12 suppositories, NDC 42494-301-12

Box of 24 suppositories, NDC 42494-301-24

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

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

NDC 42494-301-12

Hydrocortisone Acetate Suppositories

25 mg

FOR RECTAL USE ONLY

12 Suppositories
Unit Dose

Rx Only





DESCRIPTION: Each suppository contains hydrocortisone acetate 25 mg in a specially blended hydrogenated vegetable oil base.

FOR RECTAL ADMINISTRATION.

DIRECTIONS:

1. Detach one suppository from the strip of suppositories.
2. Hold suppository upright and carefully separate tabs at top opening and pull downward from the pointed end to expose the suppository.
3. Remove the suppository from the pocket.
4. Avoid excessive handling of suppository which is designed to melt at body temperature.
5. Insert one suppository rectally, pointed end first as directed in dosage and administration.

DOSAGE and ADMINISTRATION: See enclosed package insert for complete prescribing information before use.

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.

WARNING: 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, therefore all products, be subject to state and federal product has not been subjected to other equivalency testing or bioequivalence or therapeutic recommending a prescriber, product shall make such his/her professional knowledge evaluating the active ingredients and chemical ingredients enclosed prescribing information.

Manufactured for:
Cameron Pharmaceuticals
Louisville, KY 40245

Rev 07/16

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CAMERON™
PHARMACEUTICALS

NDC 42494-301-12

**Hydrocortisone Acetate
Suppositories 25 mg**
12 Suppositories



CAMERON™
PHARMACEUTICALS
NDC 42494-301-12

**Hydrocortisone Acetate
Suppositories 25 mg**
12 Suppositories

NDC 42494-301-12

**Hydrocortisone Acetate
Suppositories**

25 mg

FOR RECTAL USE ONLY

**12 Suppositories
Unit Dose**



NDC 42494-301-12

Hydrocortisone A Suppositories 25

12 Suppositories

HYDROCORTISONE ACETATE

hydrocortisone acetate suppository

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42494-301
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	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:42494-301-12	12 in 1 BOX; Type 0: Not a Combination Product	05/01/2017	
2	NDC:42494-301-24	24 in 1 BOX; Type 0: Not a Combination Product	05/01/2017	

Marketing Information

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

Labeler - Cameron Pharmaceuticals, LLC (078371442)