HYDROCORTISONE ACETATE- hydrocortisone acetate suppository
Cosette Pharmaceuticals, Inc.

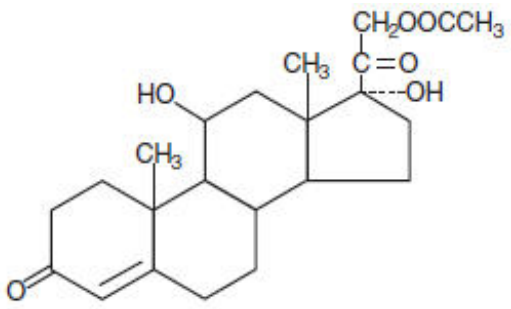
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

HYDROCORTISONE ACETATE, 30 mg
Rectal Suppositories
Rx only

DESCRIPTION

Each Hydrocortisone Acetate Suppository for rectal administration contains 30 mg hydrocortisone acetate, USP in a specially blended hydrogenated vegetable 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 $C_{23}H_{32}O_6$ 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 and Nursing Mothers

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.

It is not known whether this drug is excreted in human milk. Since 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 taking the drug, taking into account the importance of the drug to the mother.

Until adequate studies in pregnant or lactating women have been conducted, this drug should be used during pregnancy or by nursing mothers only when clearly needed and when the potential benefits outweigh the potential risks to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

ADVERSE REACTIONS

The following local adverse reactions have been reported with Hydrocortisone Acetate Suppositories:

1. Burning
2. Itching
3. Irritation
4. Dryness
5. Folliculitis
6. Hypopigmentation
7. Allergic Contact Dermatitis
8. Secondary Infection

To report SUSPECTED ADVERSE REACTIONS, contact Cosette Pharmaceuticals, Inc. at 1-800-922-1038 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.

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

Usual dosage: One suppository in the rectum twice daily 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.

HOW SUPPLIED

Hydrocortisone Acetate Suppositories are easy to open and available in cartons of:

12's NDC 0713-0493-12

Store at controlled room temperature 15° to 30° C (59° to 86° F). Store away from heat. Protect from freezing.

Distributed by:
Cosette Pharmaceuticals, Inc.
South Plainfield, NJ 07080

8-0493CPLNC1
Iss. 01/2021 VC7545

PRINCIPAL DISPLAY PANEL - 30 mg Carton

NDC 0713- **0493**-12

Rx Only

Hydrocortisone Acetate Suppositories

30 mg

UNIT DOSE

12 Suppositories

FOR RECTAL USE ONLY

Cosette Pharmaceuticals, Inc.

HYDROCORTISONE ACETATE

hydrocortisone acetate suppository

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0713-0493
Route of Administration	RECTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	30 mg

Inactive Ingredients

Ingredient Name	Strength
HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0713-0493-12	12 in 1 BOX	08/09/2021	
1		1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/09/2021	

Labeler - Cosette Pharmaceuticals, Inc. (116918230)

Establishment

Name	Address	ID/FEI	Business Operations
Cosette Pharmaceuticals NC Laboratories, LLC		079419931	manufacture(0713-0493) , pack(0713-0493) , label(0713-0493) , analysis(0713-0493)

Revised: 11/2023 Cosette Pharmaceuticals, Inc.