RECTACORT - HC - hydrocortisone acetate suppository
Acino Products, LLC.

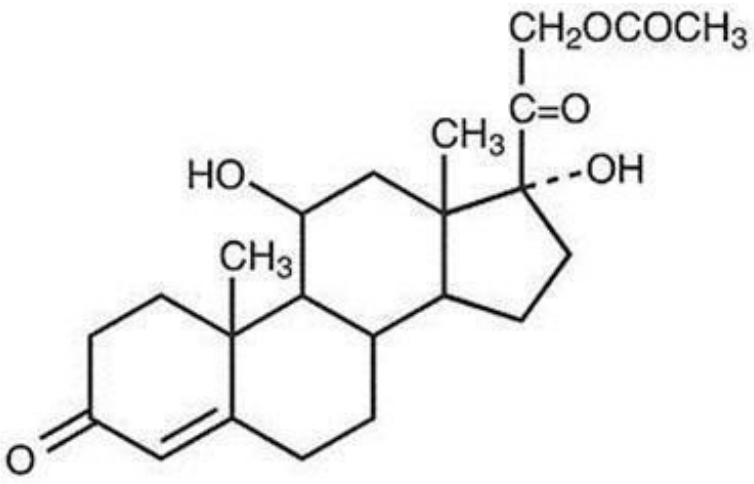
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

DESCRIPTION:

HYDROCORTISONE ACETATE, 25 mg

Rectal Suppositories

DESCRIPTION: Hydrocortisone Acetate is a corticosteroid designated chemically as pregn-4-ene-3, 20-dione, 21-(acetyloxy)-11, 17-dihydroxy-(11β) with the following structural formula:



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

CLINICAL PHARMACOLOGY:

In normal subjects, about 26% of hydrocortisone acetate is absorbed when the 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 vasconstrictive action.

INDICATIONS AND USAGE:

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

CONTRAINDICATIONS:

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; and other inflammatory conditions of anorectum and pruritus ani.

PRECAUTIONS:

Do not use hydrocortisone acetate suppositories unless a 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 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 hydrocortisone acetate suppositories; burning, itching, irritation, dryness, folliculitis, hypopigmentation, allergic contact dermatitis, 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:

For rectal administration. Detach one suppository from strip of suppositories. Remove the wrapper. Avoid excessive handling of the suppository which is designed to melt at body temperature. Insert suppository into the rectum with gentle pressure, 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 suppository is off-white, smooth surfaced and rod shaped with one pointed end. Box of 12, 24, 50, 100 suppositories.

Store between 15°-30°C(59°-86°F). Protect from freezing

Rectacort-HC Product Label

NDC 68784-108-12

Rectacort - HC
25-mg Suppositories
(Hydrocortisone Acetate in a Hydrogenated Cocoglyceride Base)

Caution: Federal Law prohibits dispensing without prescription.

Place Rx Label Here

Acino Products

12 SUPPOSITORIES

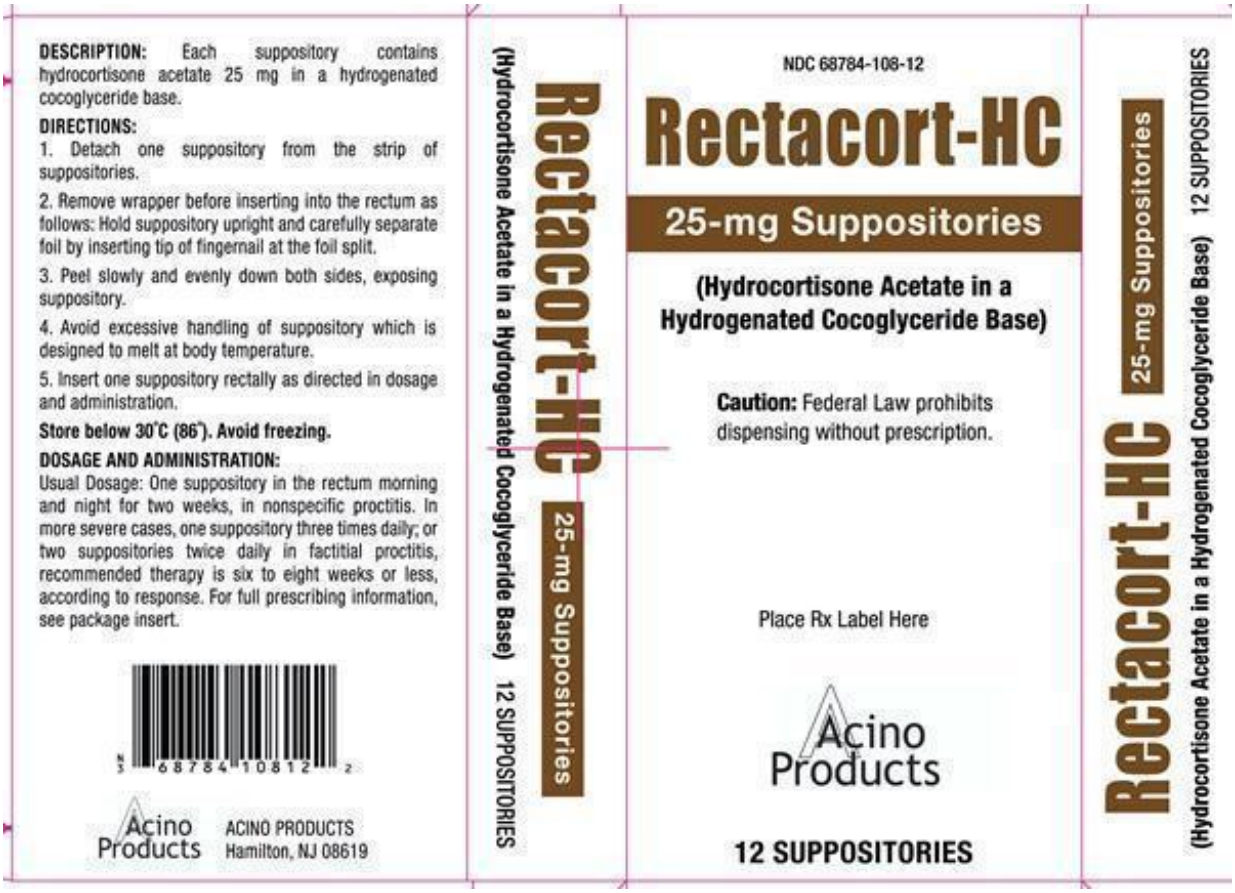
DESCRIPTION: Each suppository contains hydrocortisone acetate 25 mg in a hydrogenated cocoglyceride base.

DIRECTIONS:
1. Detach one suppository from the strip of suppositories.
2. Remove wrapper before inserting into the rectum as follows: Hold suppository upright and carefully separate foil by inserting tip of fingernail at the foil split.
3. Peel slowly and evenly down both sides, exposing suppository.
4. Avoid excessive handling of suppository which is designed to melt at body temperature.
5. Insert one suppository rectally as directed in dosage and administration.

Store below 30°C (86°F). Avoid freezing

DOSAGE AND ADMINISTRATION:
Usual Dosage: One suppository in the rectum morning and night for two weeks, in nonspecific procititis. 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. For full prescribing information, see packet insert.

ACINO PRODUCTS Hamilton, NJ 08619



Rectacort - HC Package Insert

HYDROCORTISONE ACETATE, 25 mg

Rectal Suppositories

Manufactured by:
Acino Products, LLC
Hamilton, NJ 08691 Rev. 03/14

HYDROCORTISONE ACETATE, 25 mg
Rectal Suppositories

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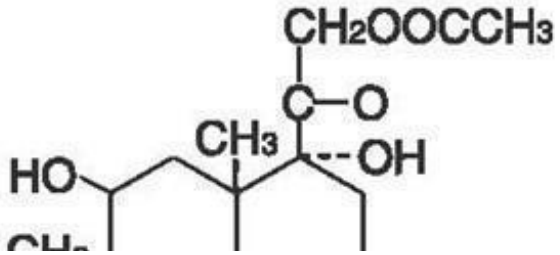

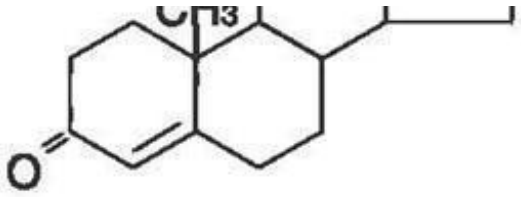

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INDICATIONS AND USAGE: Hydrocortisone acetate suppositories are indicated for use in inflamed hemorrhoids, post-irradiation (factitial) proctitis; as an adjunct in the treatment of chronic ulcerative colitis; cryptitis; and other inflammatory conditions 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.

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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.

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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.

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Acino Products, LLC
Hamilton, NJ 08691

Rev. 03/14

RECTACORT - HC

hydrocortisone acetate suppository

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68784-108
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**
HYDROGENATED COCO-GLYCERIDES (UNII: XDD37N2GPR)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68784-108-12	12 in 1 BOX		
1		1 in 1 BLISTER PACK		
2	NDC:68784-108-24	24 in 1 BOX		
2		1 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/01/2006	

Labeler - Acino Products, LLC. (019385518)

Registrant - Acino Products, LLC. (019385518)

Establishment

Name	Address	ID/FEI	Business Operations
Acino Products, LLC.		019385518	manufacture(68784-108)

Revised: 6/2014 Acino Products, LLC.