HYDROCORTISONE ACETATE- hydrocortisone acetate suppository
Rising Pharma Holdings, 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
Hydrocortisone Acetate Suppositories, 30 mg

For Rectal Administration

Rx only

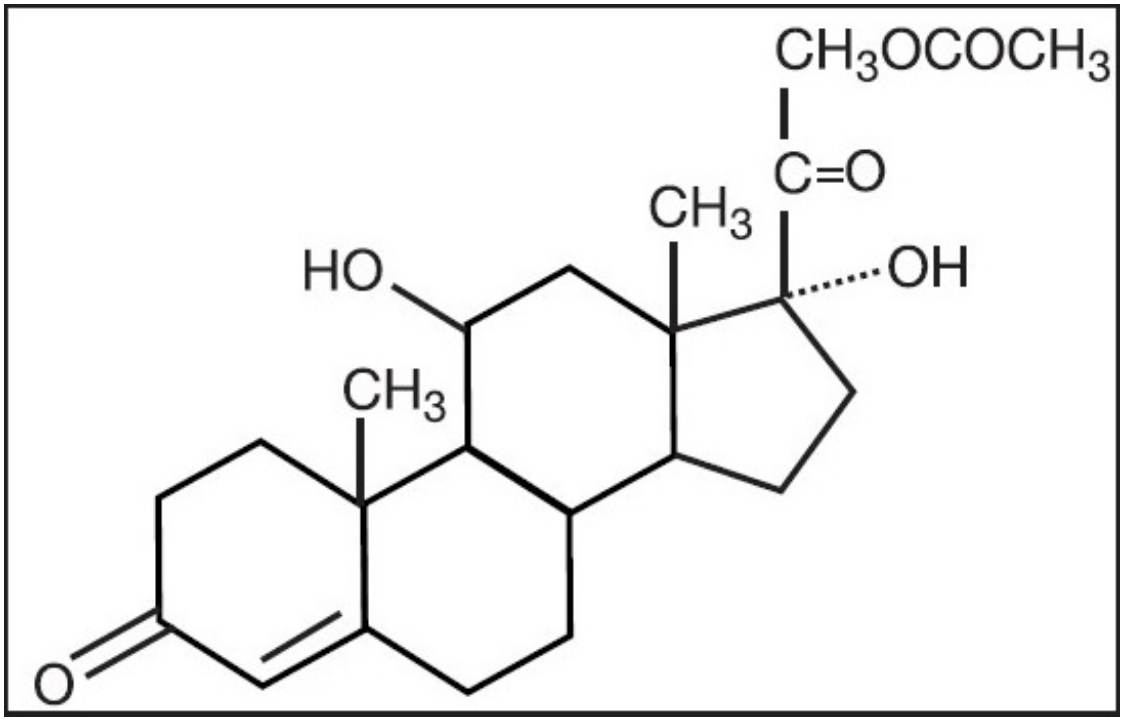
DESCRIPTION

Each Hydrocortisone Acetate Suppository for rectal administration contains 25 mg hydrocortisone acetate, USP in a specially blended hydrogenated vegetable oil base.

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-, (11ß)- with an empirical formula of C H O and the following structural formula:



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 SUSPECTED ADVERSE REACTIONS, contact Rising Pharma Holdings, Inc. at 1-844-874-7464, 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 25 mg are off-white, smooth surfaced and bullet shaped with one pointed end.
Box of 12 suppositories, NDC 16571-676-21
Box of 24 suppositories, NDC 16571-676-42

Hydrocortisone acetate suppositories 30 mg are off-white, smooth surfaced and bullet shaped with one pointed end.
Box of 12 suppositories, NDC 16571-164-21

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

Distributed by:
Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Manufactured by:
Quagen Pharmaceuticals LLC
West Caldwell, NJ 07006

52030/52050
Revised: 02/2024

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Rising® **NDC 16571-676-21**
Hydrocortisone Acetate Suppositories
25 mg

For Rectal Administration

12 Adult Suppositories **Rx only**

Rising® **NDC 16571-164-21**

Hydrocortisone Acetate Suppositories
30 mg

For Rectal Administration

12 Adult Suppositories **Rx only**

HYDROCORTISONE ACETATE

hydrocortisone acetate suppository

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16571-676
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**
HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP)	

Product Characteristics			
Color	WHITE	**Score**	
Shape	BULLET	**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:16571-676-21	12 in 1 CARTON; Type 0: Not a Combination Product	02/01/2021	
2	NDC:16571-676-42	24 in 1 CARTON; Type 0: Not a Combination Product	02/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/01/2021	

HYDROCORTISONE ACETATE

hydrocortisone acetate suppository

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16571-164
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)	

Product Characteristics			
Color	white	**Score**	
Shape	BULLET	**Size**	
Flavor		**Imprint Code**	

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16571-164-21	12 in 1 CARTON; Type 0: Not a Combination Product	03/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/01/2024	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Establishment

Name	Address	ID/FEI	Business Operations
QUAGEN PHARMACEUTICALS LLC		080281331	MANUFACTURE(16571-676, 16571-164) , PACK(16571-676, 16571-164)

Revised: 2/2024 Rising Pharma Holdings, Inc.