

HYDROCORTISONE ACETATE- hydrocortisone acetate suppository Bryant Ranch Prepack

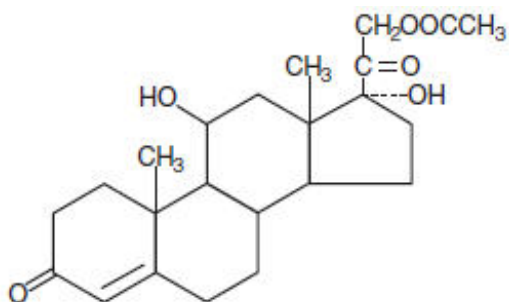
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Hydrocortisone Acetate Suppositories

DESCRIPTION

Each Hydrocortisone Acetate Suppository for rectal administration contains hydrocortisone acetate in a hydrogenated cocoglyceride 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-, (11 β)- with an empirical formula of C₂₃H₃₂O₆ 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, the corticosteroid 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. 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 corticosteroid suppositories: burning, itching, irritation, dryness, folliculitis, hypopigmentation, allergic contact dermatitis, and secondary infection.

To report SUSPECTED ADVERSE REACTIONS, contact Perrigo at 1-866-634-9120 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 overdose 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 the response of the individual case.

HOW SUPPLIED

Hydrocortisone Acetate Suppositories are easy to open, color coded and available in cartons of 12.

30 mg NDC 63629-2531-1

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from freezing.

Repackaged/Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504

Rx Only

Manufactured By
Perrigo[®]
Minneapolis, MN 55427
2201371 1B400 RC J1 Rev 07-19 B

Hydrocortisone Acetate 30 mg Suppos #12



GTIN
Lot
Exp
SN

Each rectal suppository contains: 30 mg hydrocortisone acetate USP in a hydrogenated cocoglyceride base.

Keep this and all medication out of the reach of children.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

For Rectal Use Only.

NDC 63629-2531-1

**Hydrocortisone Acetate
Suppositories**

30 mg



Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504 USA

Rx only
12 Rectal Suppositories

Manufactured by:
Perrigo

6362925311



HYDROCORTISONE ACETATE

hydrocortisone acetate suppository

Product Information

Product Type	HUMAN PRESCRIPTION	Item Code	NDC:63629-2531(NDC:0574-
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Product Type	DRUG	(Source)	7093)	
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:63629-2531-1	12 in 1 BOX	04/28/2021	
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			07/01/1990	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment			
Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-2531) , RELABEL(63629-2531)