HYDROCORTISONE ACETATE- hydrocortisone acetate suppository
Vitruvias Therapeutics

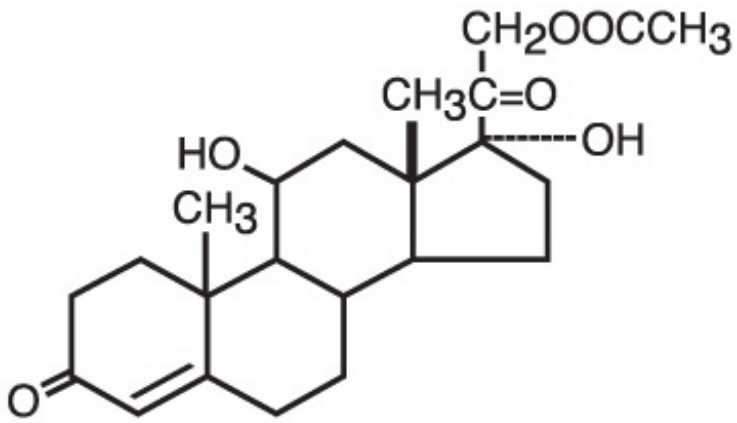
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

HYDROCORTISONE ACETATE 25MG
Rectal suppositories

Description

Each Rectal Suppository contains 25 mg hydrocortisone acetate in a hydrogenated vegetable oil base.

Hydrocortisone acetate is a corticosteroid. Chemically, hydrocortisone acetate is pregn–4–ene–3, 20–dione, 21–(acetyloxy)–11, 17–dihydroxy (11ß)– with 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, 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 the anorectum, and pruritus ani.

Contraindication

Hydrocortisone suppositories are contraindicated in those patients with a history of hypersensitivity to any of the components.

Precautions

1. Do not use unless adequate proctologic examination is made.

2. If irritation develops, the product should be discontinued and appropriate therapy instituted.

3. 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.

Carcinogenic

No long–term studies in animals have been performed to evaluate the carcinogenic potential of corticosteroid suppositories.

Information for Patients

Staining of fabric may occur with use of the suppository. Precautionary measures are recommended.

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 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 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 suppositories: Burning, itching, irritation, dryness, folliculitis, hypopigmentation, allergy contact dermatitis, secondary infection.

To report suspected adverse reactions, contact Vitruvias Therapeutics at 1–844–451–5944 or FDA @ 1–800–FDA–1088 or www.fda.gov/medwatch.

Drug Abuse and Dependence

Drug abuse and dependence has 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 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.

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **Please NOTE: This is not an Orange Book product and has not been subjected to FDA therapeutic or other equivalency testing. No representation is made as to generic status or bioequivalency.** 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 provided herein.

How is hydrocortisone acetate Suppository Supplied

Hydrocortisone acetate 25 mg Suppositories are off–white, cylinder shaped, with one end tapered. Package of 12 suppositories (NDC 69680–144–12) and package of 24 suppositories (NDC 69680–144–24).

Store at 20°-25°C (68°-77°F). See USP Controlled Temperature. Store away from heat. Protect from freezing.

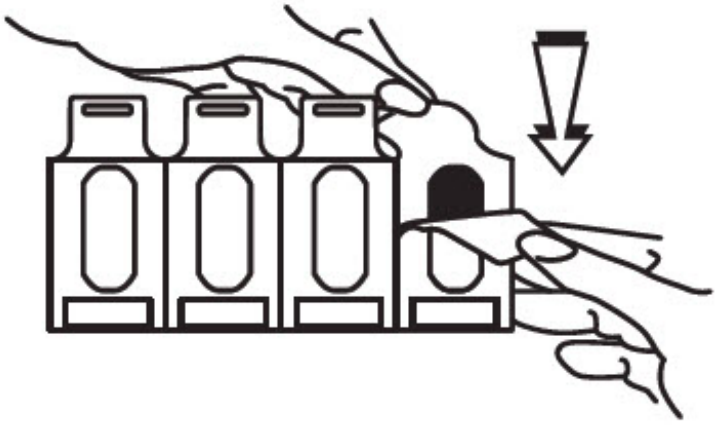
Rx only.

Opening Instructions

Avoid excessive handling of the suppository. It is designed to melt at body temperature.

1. Separate plastic film at top opening and pull downward.

2. Continue pulling downward to almost the full length of the suppository.



3. Gently remove the suppository from the film pocket.

Manufactured by:
Graxcell Pharmaceutical, LLC.
136 Oak Drive
Syosset , NY 11791

Manufactured for:
Vitruvias Therapeutics
Auburn, AL 36830

I144 0321R0

Revised 03/2021

PRINCIPAL DISPLAY PANEL - 25 mg Suppository Blister Pack Carton

NDC 69680-144-12

VITRUVIAS
therapeutics

Hydrocortisone Acetate
Suppositories 25 mg

Rx only

12 Suppositories

NDC 69680-144-12

VITRUVIAS therapeutics

Hydrocortisone Acetate Suppositories 25 mg

Rx only

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Hydrocortisone Acetate Suppositories 25 mg

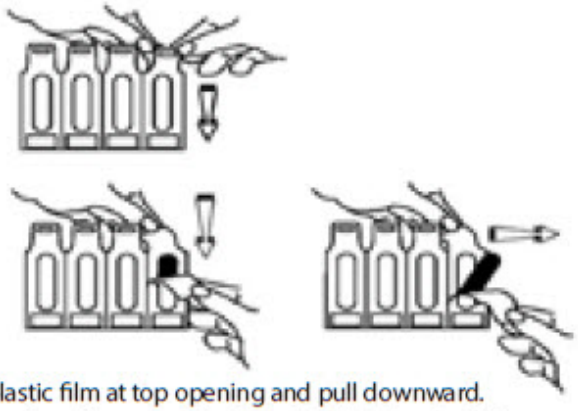
VITRUVIAS therapeutics

Hydrocortisone Acetate Suppositories 25 mg

Each suppository contains: Hydrocortisone acetate 25 mg in a specially blended hydrogenated vegetable oil base. FOR RECTAL ADMINISTRATION.

DOSAGE AND ADMINISTRATION: Read package insert for complete information before use.

DIRECTIONS FOR USE:



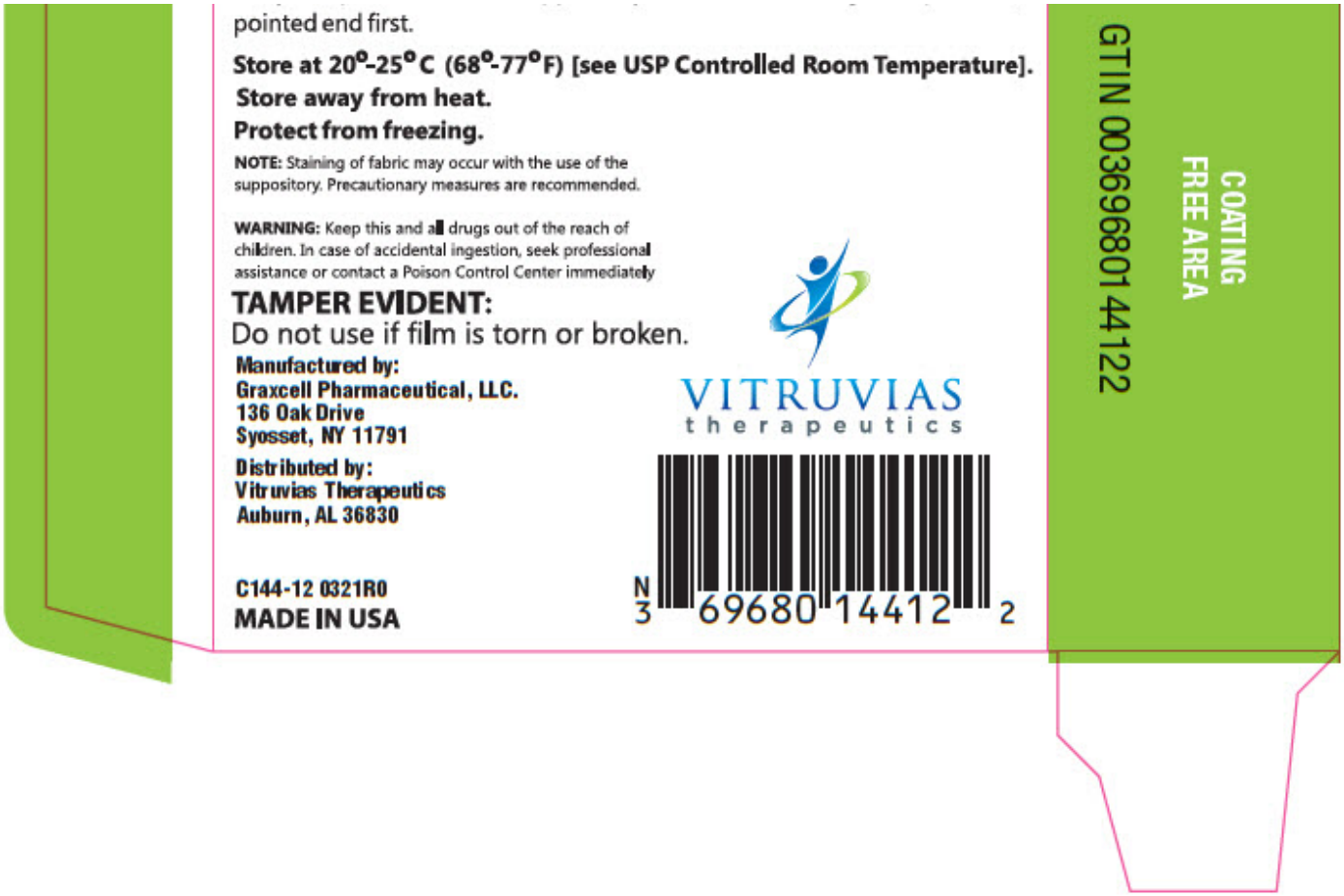
1. Separate plastic film at top opening and pull downward.
2. Continue pulling downward to almost the full length of the suppository.
3. Gently remove the suppository from the film pocket.

Avoid excessive handling of the suppository, which is designed to melt at body temperature. Insert suppository into rectum with gentle pressure,

COATING FREE AREA

Hydrocortisone Acetate Suppositories 25 mg

12 Suppositories



HYDROCORTISONE ACETATE

hydrocortisone acetate suppository

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69680-144
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 COCO-GLYCERIDES (UNII: XDD37N2GPR)	

Product Characteristics			
Color	WHITE (off-white)	**Score**	
Shape	BULLET	**Size**	

Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69680-144-12	2 in 1 CARTON	06/01/2021	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69680-144-24	4 in 1 CARTON	06/01/2021	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		06/01/2021	

Labeler - Vitruvias Therapeutics (079200795)

Establishment

Name	Address	ID/FEI	Business Operations
Graxcell Pharmaceutical, LLC.		080805631	MANUFACTURE(69680-144) , ANALYSIS(69680-144) , PACK(69680-144)

Revised: 6/2021 Vitruvias Therapeutics