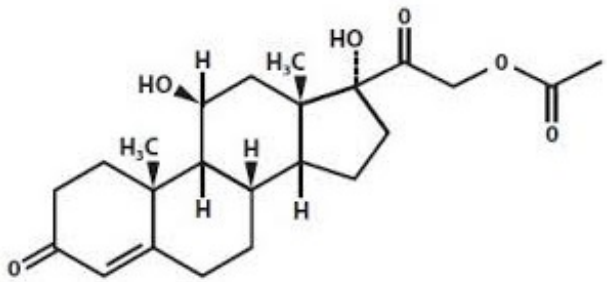
HYDROCORTISONE ACETATE- hydrocortisone acetate suppository
GRAXCELL PHARMACEUTICAL, LLC.

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.

HYDROCORTISONE ACETATE SUPPOSITORY 25MG, 70795-2412

Graxcell Pharmaceutical, llc.
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labelling has not been approved by FDA.
Hydrocortisone acetae, 25mg.
Rectal suppositories.



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

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.

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.

Hydrocortisone Acetate suppositories are contraindicated in those patients having a history of hypersensitivity to hydrocortisone acetate or any of the components

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.

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

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

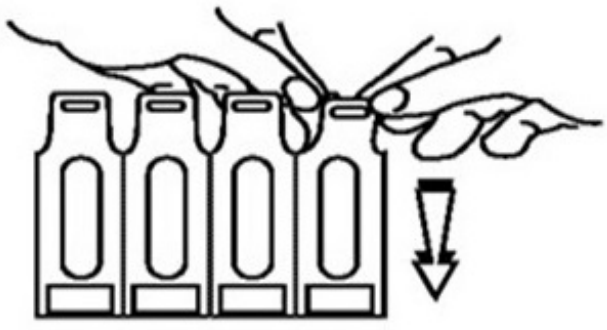
Graxcell pharmaceutical, llc.

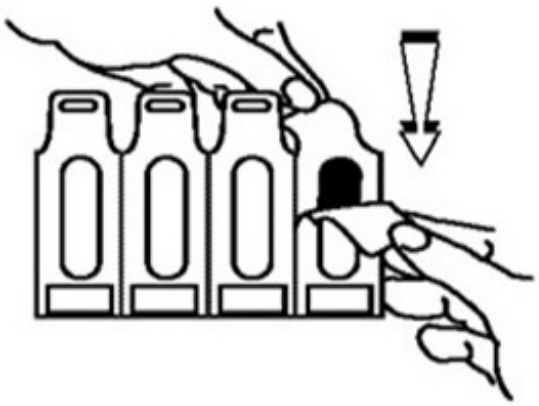
1-888-266-8818 or

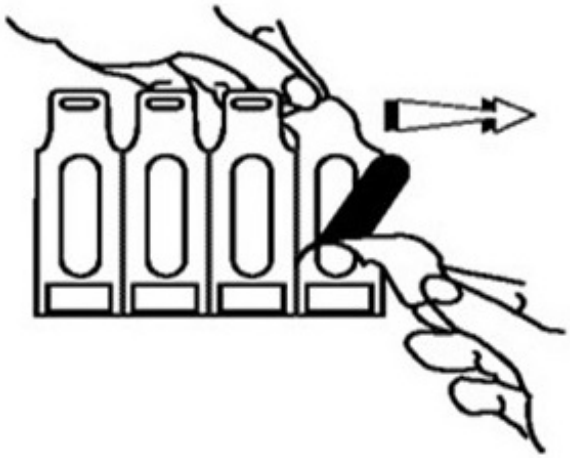
FDA @ 1-800-FDA-1088 or

www.fda.gov/medwatch

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







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 in six to eight weeks or less, according to the response of the individual case.

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 suppsitory from the film pocket.

Hydrocortisone Acetate suppositories 25mg are white,cyclinder shaped, with one end tapered.

Package of 12 NDC 70795-2412-1

and

Package of 24 NDC 70795-2412-2

Store at 20º-25ºC (68º-77ºF) [See USP Controlled Room Temperature]. Store away from heat. Protect from freezing.

Manufactured for:

Graxcell pharmaceutical, LLC.

130 knickerbocker ave,Bohemia, NY 11716

Manufactured by:

Graxcell pharmaceutical, llc.

136 OAk Drive,

syosset, NY 11791

1-888-266-8818.

Drug abuse and dependece have not been reported in patients treated with Hydrocortisone acetate suppositories.

24 Suppositories

Hydrocortisone acetate suppositories 25mg

GRAXCELL PHARMACEUTICAL, LLC.

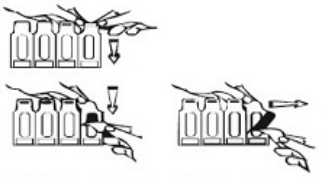
COATING FREE AREA

Hydrocortisone acetate suppositories 25mg

Each suppository contains: Hydrocortisone acetate 25mg 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, pointed end first.

Store at 20-25 0 C (68-77 0 F) [see USP Controlled Room Temperature]. Store away from heat.
Protect from freezing.

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

WARNING: 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

TEMPER EVIDENT:
Do not use if film is torn or broken.

Manufactured by:
GRAXCELL Pharmaceutical LLC
136 OAK Drive
Syosset , N.Y. 11791
1-888-266-8818

Distributed by:
GRAXCELL Pharmaceutical LLC
130 Knickerbocker Ave
Bohemia, NY 11716

GRAXCELL PHARMACEUTICAL, LLC.

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24 Suppositories

Hydrocortisone acetate suppositories 25mg

GRAXCELL PHARMACEUTICAL, LLC.

Lot:
Exp:

NC

MPS

NDC 70795-2412-2

GRAXCELL PHARMACEUTICAL, LLC.

Hydrocortisone acetate suppositories 25mg

Rx only

24 Suppositories

Hydrocortisone acetate suppositories 25mg
24 Suppositories

GRAXCELL PHARMACEUTICAL, LLC.

Hydrocortisone acetate suppositories 25mg

24 Suppositories

31

HYDROCORTISONE ACETATE

hydrocortisone acetate suppository

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70795-2412
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	yellow (off-white)	**Score**	
Shape	BULLET	**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70795-2412-1	12 in 1 CARTON; Type 0: Not a Combination Product	10/18/2017	
2	NDC:70795-2412-2	24 in 1 CARTON; Type 0: Not a Combination Product	10/18/2017	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
unapproved drug other		10/18/2017	

Labeler - GRAXCELL PHARMACEUTICAL, LLC. (056556923)

Revised: 12/2021 GRAXCELL PHARMACEUTICAL, LLC.