HYDROCORTISONE ACETATE- hydrocortisone acetate suppository
Paddock Laboratories, LLC

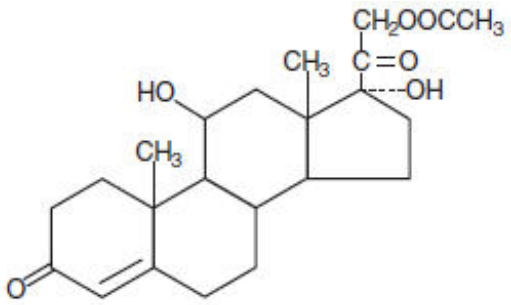
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Hydrocortisone Acetate
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-, (11β)- with an empirical formula of $C_{23}H_{32}O_6$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 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 the response of the individual case.

HOW SUPPLIED

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

25 mg NDC 0574-7090-12

30 mg NDC 0574-7093-12

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

Rx Only

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

PRINCIPAL DISPLAY PANEL - 25 mg Carton

Rx Only

NDC 0574-7090-12

Hydrocortisone Acetate Suppositories

25 mg

UNIT DOSE

12 Suppositories

FOR RECTAL USE ONLY

The following image is a placeholder representing the product identifier that is either affixed or imprinted on the drug package label during the packaging operation.

S/N [insert product's serial number]
Lot [insert product's lot number]
Exp [insert product's expiration date]

PRINCIPAL DISPLAY PANEL – 30mg Carton

Rx Only

NDC 0574-7093-12

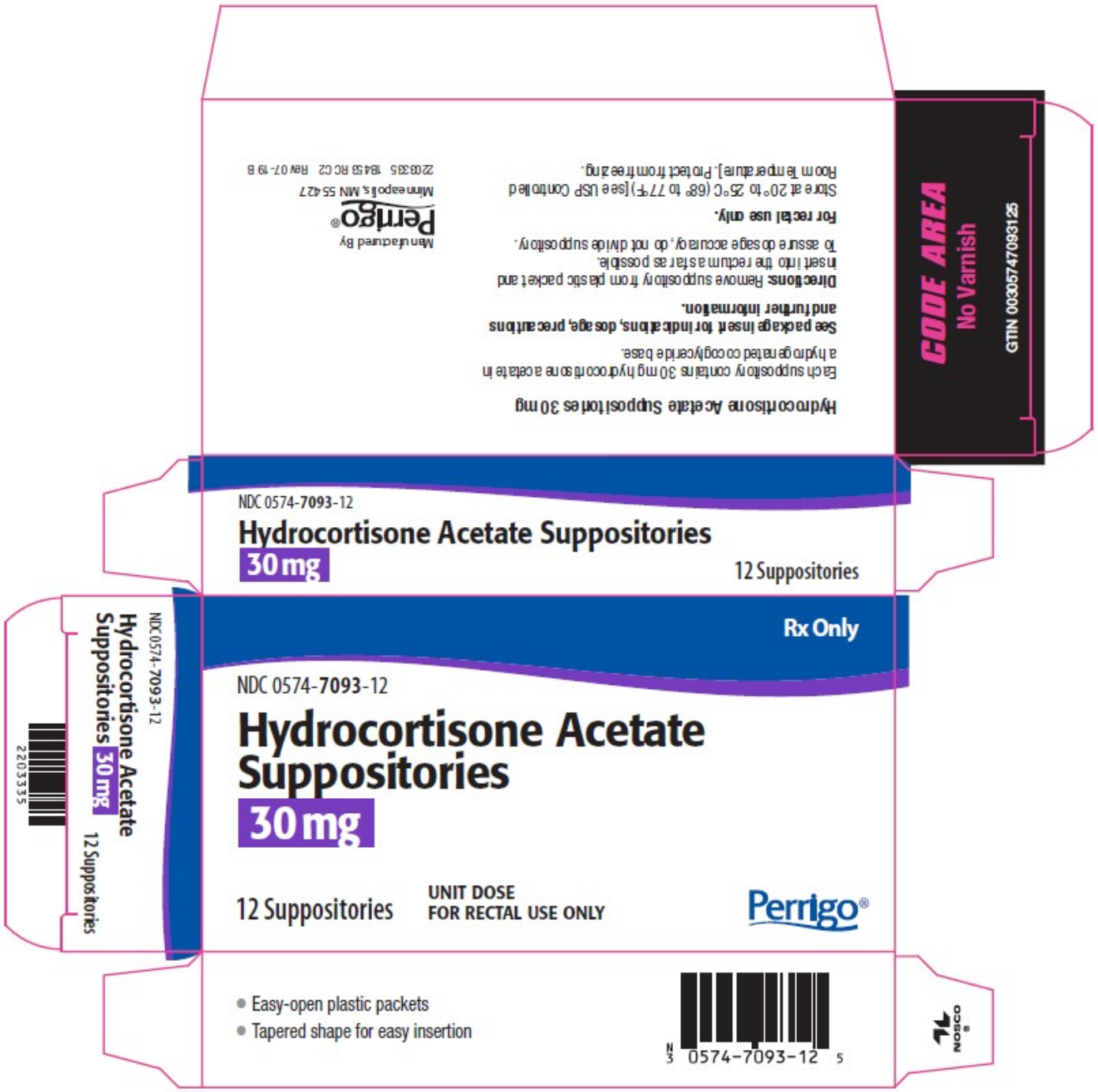
Hydrocortisone Acetate Suppositories

30 mg

UNIT DOSE

12 Suppositories

FOR RECTAL USE ONLY



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HYDROCORTISONE ACETATE

hydrocortisone acetate suppository

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0574-7090
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 PALM KERNEL OIL (UNII: FM8D1RE2VP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0574-7090-12	12 in 1 BOX	07/01/1990	
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	

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Labeler - Paddock Laboratories, LLC (967694121)

Revised: 5/2020 Paddock Laboratories, LLC