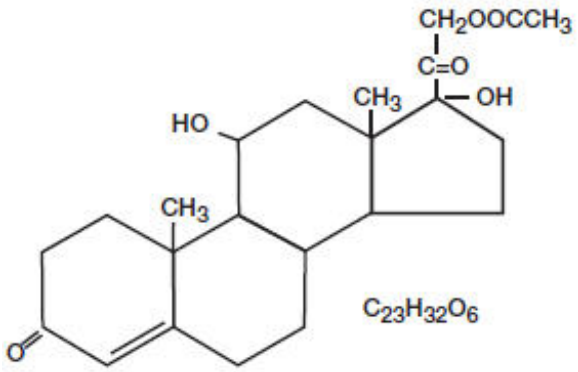
HYDROCORTISONE ACETATE- hydrocortisone acetate suppository
Syntenza Pharmaceuticals LLC

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, 25 mg
Rectal Suppositories

DESCRIPTION

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:



MW 404.51

Each rectal suppository contains hydrocortisone acetate, USP 25 mg in a specially blended hydrogenated vegetable oil base.

CLINICAL PHARMACOLOGY

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 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; and 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.

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 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 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 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

For rectal administration. Detach one suppository from strip of suppositories. Hold suppository upright. Separate tabs at top opening and pull downward from the pointed end. Continue pulling downward to almost the full length of the suppository. Carefully remove the suppository from the pocket. Avoid excessive handling of the suppository which is designed to melt at body temperature. Insert suppository into the rectum with gentle pressure, pointed end first. Insert one suppository in the rectum twice daily, morning and night for two weeks, in nonspecific proctitis. In more severe cases, one suppository three times a day or two suppositories twice daily. In factitial proctitis, the recommended duration of therapy is six to eight weeks or less, according to the response of the individual case.

HOW SUPPLIED

Boxes of 12 suppositories	NDC 72056-010-12
Boxes of 24 suppositories	NDC 72056-010-24

Rx only.

STORAGE AND HANDLING

Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]. **Store away from heat.** Protect From Freezing.

Manufactured for:
Syntenza Pharmaceuticals LLC
Edina, MN 55436, USA

Rev. 06/18

PRINCIPAL DISPLAY PANEL - 25 mg Suppository Blister Pack Carton

SYNTENZA

NDC 72056-010-12

Hydrocortisone Acetate
Suppositories 25 mg

12 Adult Suppositories

Rx only
For Rectal Administration

HYDROCORTISONE ACETATE

hydrocortisone acetate suppository

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72056-010
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)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	BULLET	**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72056-010-12	2 in 1 CARTON	06/20/2018	
1	NDC:72056-010-06	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:72056-010-24	4 in 1 CARTON	06/20/2018	
2	NDC:72056-010-06	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		06/20/2018	

Labeler - Syntenza Pharmaceuticals LLC (080999747)

Revised: 7/2018 Syntenza Pharmaceuticals LLC