HYDROCORTISONE ACETATE- hydrocortisone acetate suppository
A-S Medication Solutions

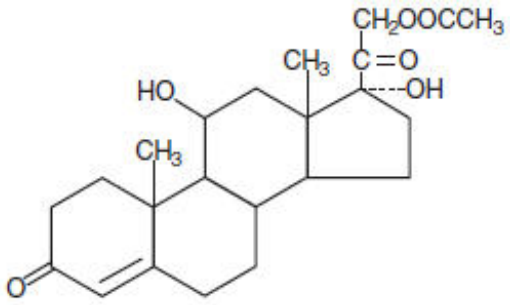
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Hydrocortisone Acetate
Suppositories 25 mg

DESCRIPTION

Each suppository for rectal administration contains 25 mg hydrocortisone acetate USP in a hydrogenated cocoglyceride base. Hydrocortisone acetate is a corticosteroid.

Chemically, hydrocortisone acetate is pregn-4-ene-3, 20 dione, 21- (acetyloxy)-11, 17-dihydroxy-, (11β)- 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, antipruritic and vasoconstrictive action.

INDICATIONS AND USAGE

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.

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.

It is not known whether this drug is excreted in human milk.

Until adequate studies in pregnant or lactating women have been conducted, this drug should be used during pregnancy or by nursing mothers only when clearly needed and when the potential benefits outweigh the potential risks.

ADVERSE REACTIONS

The following local adverse reactions have been reported with corticosteroid suppositories:

- Burning
- Itching
- Irritation
- Dryness
- Folliculitis
- Hypopigmentation
- Allergic Contact Dermatitis
- Secondary Infection

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 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 response.

HOW SUPPLIED

Product: 50090-0381

NDC: 50090-0381-0 1 SUPPOSITORY in a PACKET / 12 in a BOX

Manufactured By
Perrigo®
Minneapolis, MN 55427
(01-12)

HYDROCORTISONE ACETATE

HYDROCORTISONE ACETATE

hydrocortisone acetate suppository

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:50090-0381(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

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	BULLET	**Size**	35mm
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50090-0381-0	12 in 1 BOX	06/29/2016	
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 - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-0381)

Revised: 1/2019 A-S Medication Solutions