

**HYDROCORTISONE ACETATE- hydrocortisone acetate suppository**  
**Central Texas Community Health Centers**

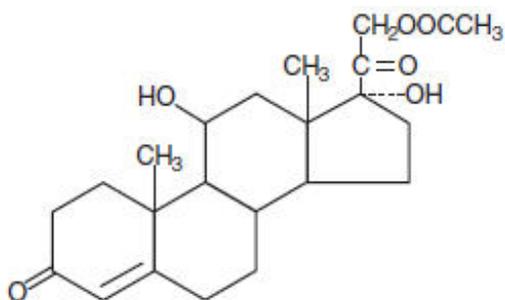
*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).*

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**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-, (11 $\beta$ )- 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 (factual) 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



Minneapolis, MN 55427  
(01-12)

**PRINCIPAL DISPLAY PANEL - 12 Packet Box Label**

CommUnityCare Federally Qualified Health Centers

HYDROCORTISONE  
SUPP.25MG # 12

Date:

Name:  
Dr.

USE AS DIRECTED BY DOCTOR.

123456

1/1/01

Hydrocortisone Supp. 25 mg #12 NDC 76413-132-12

Batch: 123456

Lot: 123456

Exp: 1/1/01

PERRIGO

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

CommUnityCare Federally Qualified Health Centers

HYDROCORTISONE  
SUPP.25MG # 12

Date:

Name: Dr.

USE AS DIRECTED BY DOCTOR.

USO COMO DIRIGIDO POR MEDICO.

123456

1/1/01

Hydrocortisone Supp. 25 mg #12 NDC 76413-132-12

Batch: 123456

Lot: 123456

Exp: 1/1/01

PERRIGO

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**HYDROCORTISONE ACETATE**

hydrocortisone acetate suppository

**Product Information**

**Product Type**

HUMAN PRESCRIPTION DRUG

**Item Code (Source)**

NDC:76413-132(NDC:0574-7090)

<b>Route of Administration</b>	RECTAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	25 mg	
<b>Product Characteristics</b>				
<b>Color</b>	WHITE	<b>Score</b>	no score	
<b>Shape</b>	BULLET	<b>Size</b>	35mm	
<b>Flavor</b>		<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:76413-132-12	12 in 1 BOX	07/01/1990	
1		1 in 1 PACKET; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
UNAPPROVED DRUG OTHER		07/01/1990		

**Labeler** - Central Texas Community Health Centers (079674019)

### Establishment

Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-132) , RELABEL(76413-132)

Revised: 4/2016

Central Texas Community Health Centers