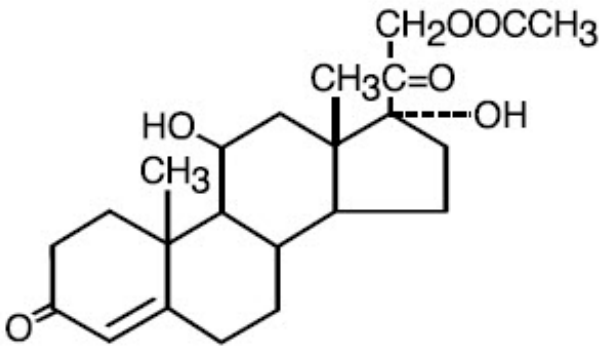
ANUSOL HC- hydrocortisone acetate suppository
Salix Pharmaceuticals, Inc

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.

Anusol-HC™Hydrocortisone Acetate Rectal Suppositories, 25 mg
Rx only

DESCRIPTION

Each Anusol-HC™ 25 mg Suppository contains 25 mg hydrocortisone acetate in a hydrogenated vegetable oil base. Hydrocortisone acetate is a corticosteroid. Chemically, hydrocortisone acetate is pregn-4-ene-3, 20-dione, 21-(acetyloxy)-11, 17-dihydroxy (11ß)- 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, anti-pruritic 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.

CONTRAINDICATION

Anusol-HC™ 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.

Information for Patients:

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

Pregnancy:

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. Anusol-HC™ suppositories should only be used during pregnancy if the potential benefit justifies the risk of the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers:

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 Anusol-HC™ 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.

1. Burning
2. Itching
3. Irritation
4. Dryness
5. Folliculitis
6. Hypopigmentation
7. Allergic contact dermatitis
8. Secondary infection

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals, a division of Valeant Pharmaceuticals North America LLC, at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG ABUSE AND DEPENDENCE

Drug abuse and dependence has not been reported in patients treated with Anusol-HC™ 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.

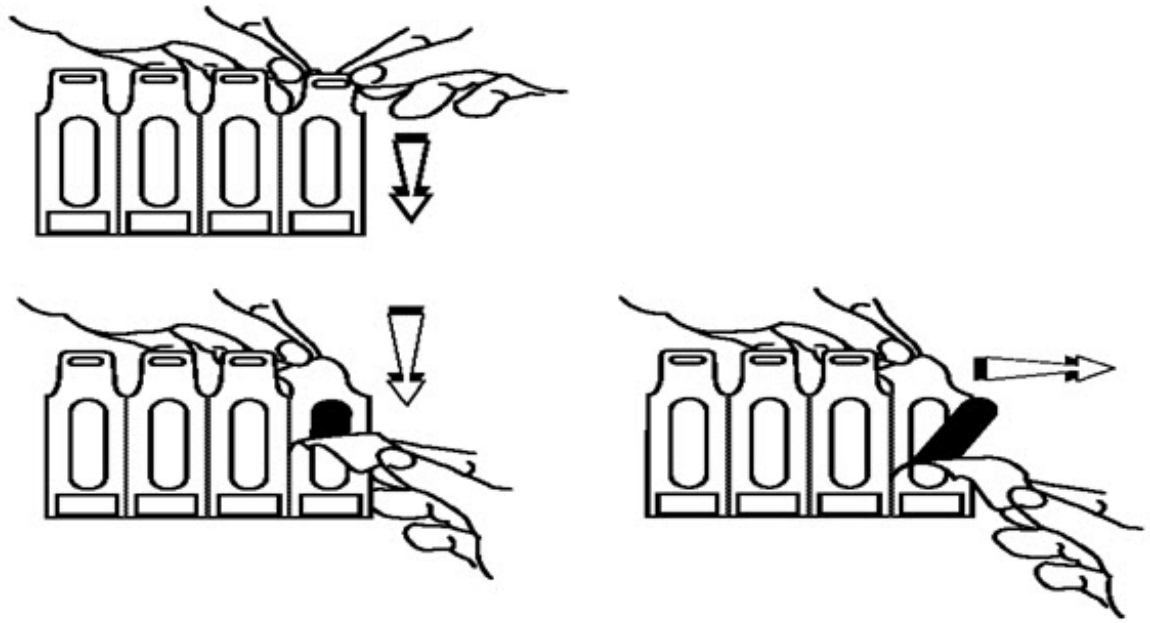
HOW SUPPLIED

Anusol-HC™ 25 mg Suppositories are white, cylinder shaped, with one end tapered.
NDC 65649-411-12 25 mg 12 suppositories
NDC 65649-411-24 25 mg 24 suppositories

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Store away from heat. PROTECT FROM FREEZING.

Manufactured for: Salix Pharmaceuticals, a division of Valeant

Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA



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 suppository from the film pocket.

Rev. 10/2017

9520701

2201318

9B500 9L J2

PACKAGE LABEL PRINCIPAL DISPLAY PANEL - Carton

NDC 65649-411-12

Rx only

Anusol-HC™

(Hydrocortisone Acetate in a

Hydrogenated Vegetable Oil Base)

For rectal use only.

Not for oral use.

12 Suppositories

ANUSOL HC

hydrocortisone acetate suppository

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65649-411
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 OIL (UNII: 257THB963H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65649-411-12	12 in 1 BOX; Type 0: Not a Combination Product	06/01/2004	
2	NDC:65649-411-24	24 in 1 BOX; Type 0: Not a Combination Product	06/01/2004	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		06/01/2004	

Labeler - Salix Pharmaceuticals, Inc (793108036)

Establishment

Name	Address	ID/FEI	Business Operations
Paddock Laboratories, LLC		967694121	MANUFACTURE(65649-411) , PACK(65649-411)

Revised: 10/2017 Salix Pharmaceuticals, Inc