

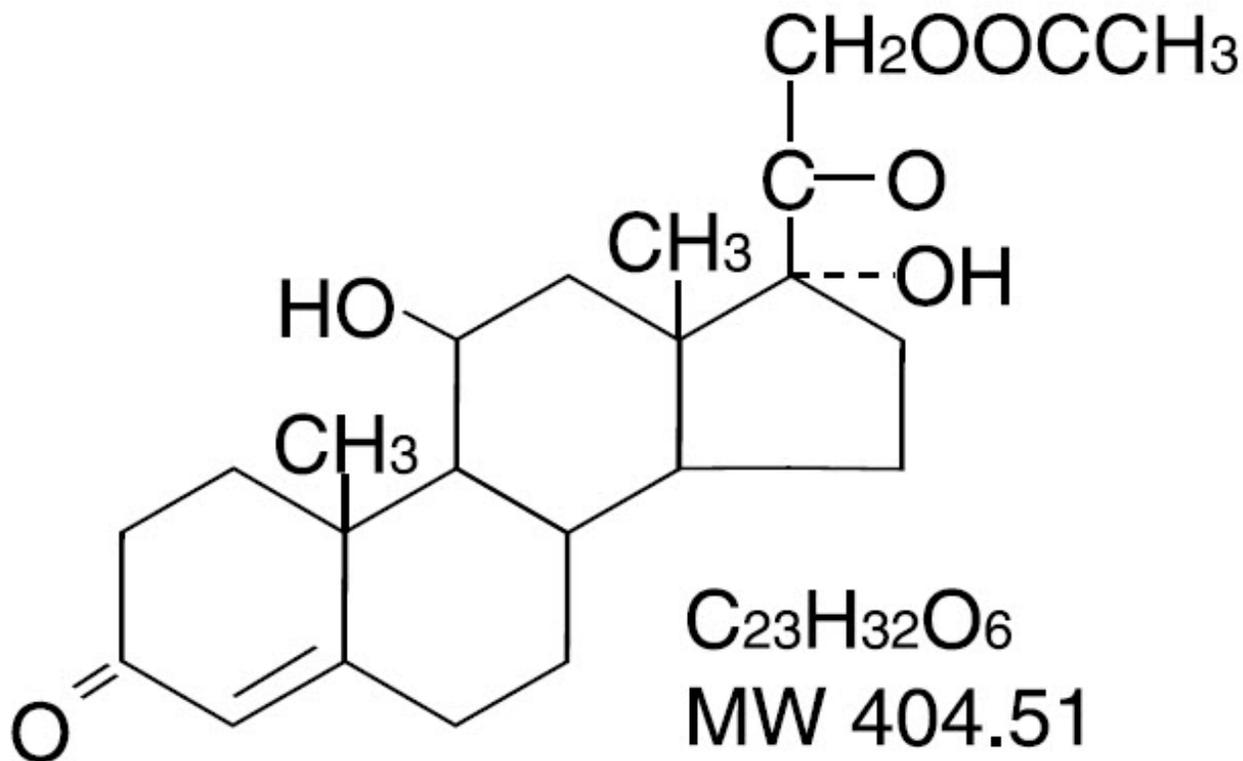
PROCTOCORT- hydrocortisone acetate suppository
Salix Pharmaceuticals, Inc

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.

PROCTOCORT®
Hydrocortisone Acetate Rectal Suppositories, 30 mg
Rx only

DESCRIPTION

Hydrocortisone Acetate is a corticosteroid designated chemically as pregn-4-ene-3, 20-dione, 21-(acetyloxy)-11, 17-dihydroxy-(11 β) with the following structural formula:



Each rectal suppository contains hydrocortisone acetate, USP 30 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

Proctocort[®] Suppositories are indicated for use in inflamed hemorrhoids, postirradiation (factual) proctitis; as an adjunct in the treatment of chronic ulcerative colitis; cryptitis; and other inflammatory conditions of anorectum and pruritus ani.

CONTRAINDICATIONS

Proctocort[®] Suppositories are contraindicated in those patients having a history of hypersensitivity to hydrocortisone acetate or any of the components.

PRECAUTIONS

Do not use Proctocort[®] 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 anti-bacterial agent should be instituted. If a favorable response does not occur promptly, Proctocort[®] Suppositories 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. Proctocort[®] 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.

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 Proctocort[®] 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 Salix Pharmaceuticals 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 have not been reported in patients treated with hydrocortisone acetate suppositories.

OVERDOSAGE

If signs and symptoms of systemic overdose occur, discontinue use.

DOSAGE AND ADMINISTRATION

For rectal administration. Detach one suppository from strip of suppositories. Remove the foil wrapper. 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

Box of 12 suppositories - 30 mg - NDC 65649-511-12

Box of 24 suppositories - 30 mg - NDC 65649-511-24

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

Distributed by: Salix Pharmaceuticals, a division of Bausch Health US, LLC,
Bridgewater, NJ 08807 USA

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**PACKAGE LABEL PRINCIPAL DISPLAY PANEL - PROCTOCORT[®] 30 mg Carton
Label**

NDC65649-511-12

Rx only

PROCTOCORT[®]

Hydrocortisone Acetate Rectal Suppositories

For rectal use only.

Not for oral use.

30 mg

12 Suppositories



PROCTOCORT

hydrocortisone acetate suppository

Product Information

| | | | |
|-------------------------|-------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:65649-511 |
| Route of Administration | RECTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | |
|--|------------------------|-------|
| HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ) | HYDROCORTISONE ACETATE | 30 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:65649-511-12 | 12 in 1 BOX; Type 0: Not a Combination Product | 06/01/2004 | |
| 2 | NDC:65649-511-24 | 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(65649-511) |

Revised: 9/2024

Salix Pharmaceuticals, Inc