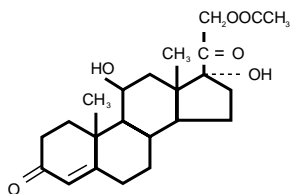


# HEMRIL<sup>®</sup>-30

## Hydrocortisone Acetate, 30 mg Suppositories

### DESCRIPTION

Each Hemril<sup>®</sup>-30 suppository contains 30 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-,(11 $\beta$ )- with the following structural formula:



### CLINICAL PHARMACOLOGY

In normal subjects, about 26% 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.

### CONTRAINDICATION

Hemril<sup>®</sup>-30 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 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. Hemril<sup>®</sup>-30 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 Hemril<sup>®</sup>-30 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.

### DRUG ABUSE AND DEPENDENCE

Drug abuse and dependence have not been reported in patients treated with Hemril<sup>®</sup>-30 suppositories.

### OVERDOSAGE

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

### DOSAGE AND ADMINISTRATION

Detach one suppository from strip of suppositories. Carefully remove the plastic wrapper and insert suppository into rectum with gentle pressure, pointed end first. For nonspecific proctitis, insert one suppository in the morning and evening for two weeks. For more severe cases, insert one suppository three times daily or two suppositories twice daily. For factitial proctitis, recommended therapy is six to eight weeks or less, according to response.

### HOW SUPPLIED

Hemril<sup>®</sup>-30 Suppositories are white, smooth surfaced, torpedo-shaped with one rounded end.

Hemril<sup>®</sup>-30 NDC 0245-0112-12 12 suppositories per carton

Hemril<sup>®</sup>-30 NDC 0245-0112-24 24 suppositories per carton

**Store at controlled room temperature, 15-30° C (59-86° F).**

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**UPSHER-SMITH**

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