

PRESCRIBING INFORMATION

ANUSOL-HC™ SUPPOSITORIES

Hydrocortisone Acetate and Zinc Sulfate Suppositories

(10 mg Hydrocortisone Acetate and 10 mg Zinc Sulfate Monohydrate)

Church & Dwight Canada Corp.
Mississauga, ON L5S 0A5

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(10 mg Hydrocortisone Acetate and 10 mg Zinc Sulfate Monohydrate)**

THERAPEUTIC CLASSIFICATION

Anorectal Therapy

INDICATIONS AND USAGE

ANUSOL-HC™ SUPPOSITORIES (Hydrocortisone Acetate and Zinc Sulfate Monohydrate) is indicated for the relief of pain and discomfort following anorectal surgery of all type and that is associated with the acute phase of common anorectal disorders. These include hemorrhoids, internal and external (including those accompanying pregnancy) whether or not complicated by thrombosis and prolapse; pruritus ani, proctitis, cryptitis, fissures, and incomplete fistulas; and other congestive allergic or inflammatory conditions.

CONTRAINDICATIONS

ANUSOL-HC™ SUPPOSITORIES (Hydrocortisone Acetate and Zinc Sulfate Monohydrate) is contraindicated in patients with a sensitivity to any of the components. Not to be used in the presence of existing tuberculous, fungal and viral lesions of the skin.

PRECAUTIONS

Until an adequate proctologic examination is completed and diagnosis made, ANUSOL-HC™ SUPPOSITORIES (Hydrocortisone Acetate and Zinc Sulfate Monohydrate) or any preparation containing hydrocortisone should not be used. In addition, specific measures against infection, allergy and other causal factors must not be neglected. Prolonged use of this medication could produce systemic corticosteroid effect although none have noted to date. As with all medication

that is applied locally, if idiosyncratic reactions occur, medication should be discontinued.

Pregnancy and Lactation:

The safe use of topical corticosteroids during pregnancy and lactation has not been fully established. Therefore, during pregnancy, ANUSOL-HC™ SUPPOSITORIES (Hydrocortisone Acetate and Zinc Sulfate Monohydrate) should not be used unnecessarily in large amounts, or for prolonged periods of time.

ADVERSE REACTIONS

Occasionally, patients may experience burning upon application of the ANUSOL-HC™ SUPPOSITORIES (Hydrocortisone Acetate and Zinc Sulfate Monohydrate) especially if the anoderm is not intact. Local sensitivity reactions have been rare.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

The chances of overdosage are very rare, and no toxic reactions or side effects have been reported with ANUSOL-HC™ SUPPOSITORIES (Hydrocortisone Acetate and Zinc Sulfate Monohydrate).

Treatment: In case of accidental ingestion, perform gastric lavage, followed by a purgative dose of magnesium sulfate.

DOSAGE AND ADMINISTRATION

Remove wrapper from the ANUSOL-HC™ SUPPOSITORIES (Hydrocortisone Acetate and Zinc Sulfate Monohydrate) and insert suppository into the rectum in the morning and at bedtime, and after each bowel movement, or as directed by a physician.

Suppository Composition

Each ANUSOL-HC™ SUPPOSITORIES contains: 10 mg hydrocortisone acetate and 10 mg Zinc Sulfate monohydrate in a triglyceride base. Non-medicinal ingredients: calcium phosphate dibasic, magnesium stearate, Hydrogenated Vegetable Oil.

Stability and Storage Recommendations

Store ANUSOL-HC™ SUPPOSITORIES (Hydrocortisone Acetate and Zinc Sulfate Monohydrate) in a cool place between 15°C and 30°C.

AVAILABILITY OF DOSAGE FORMS

ANUSOL-HC™ SUPPOSITORIES (Hydrocortisone Acetate and Zinc Sulfate Monohydrate) is available in box of 24.

PHARMACEUTICAL INFORMATION

Drug Substance

Proper Name: Hydrocortisone Acetate and Zinc Sulfate Monohydrate

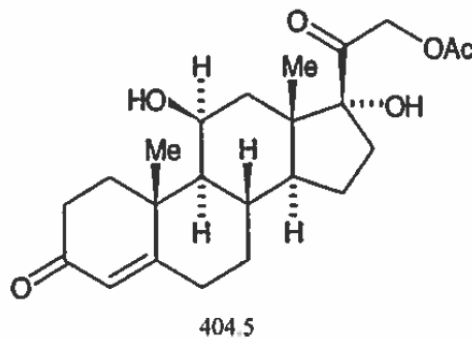
Chemical Name: Hydrocortisone Acetate - Pregn-4-ene-3,20-dione, 21-(acetyloxy)-11,17-dihydroxy-, (11 β)-.

Zinc Sulfate – Zinc sulfate (1:1) monohydrate

Empirical Formula: Hydrocortisone Acetate - $C_{23}H_{32}O_6$
Zinc Sulfate monohydrate - $ZnSO_4 \cdot H_2O$

Molecular weight: Hydrocortisone Acetate - 404.50
Zinc Sulfate monohydrate - 179.4

Structural Formula for Hydrocortisone Acetate:



Description: Hydrocortisone Acetate: White to practically white, odorless, crystalline powder. Slightly soluble in alcohol and in chloroform; insoluble in water.

Zinc Sulfate monohydrate: Colorless, transparent prisms, or small needles. The monohydrate is practically insoluble in alcohol.