ENTOFOAM Rectal Foam (Hydrocortisone acetate)

Composition

Each canister contains:
Hydrocortisone Acetate, IP ......................... 10% w/w

Dosage Form

Aerosol rectal foam

Pharmacology

Pharmacodynamics

Hydrocortisone acetate in its topical form is primarily effective because of its anti-inflammatory, anti-pruritic and vasoconstrictive action. The use of topically applied steroids in the treatment of ulcerative colitis, proctosigmoiditis and ulcerative proctitis is well known.

Pharmacokinetics

The topically applied steroid acts locally and so pharmacokinetics are not relevant to its activity.

Indications

ENTOFOAM is indicated as adjunctive therapy in the topical treatment of ulcerative proctitis, proctosigmoiditis and ulcerative colitis in patients who cannot retain hydrocortisone or other corticosteroid enemas.

Dosage And Administration

All ages

One applicator-full of foam inserted into the rectum once or twice daily for 2 or 3 weeks and then every second day thereafter.

*It should be emphasized that dosage requirements are variable and must be individualized on the basis of the disease under treatment and the response of the patient.* After a favorable response is noted, the proper maintenance dosage should be determined by decreasing the initial drug dosage in small decrements at appropriate time intervals until the lowest dosage that will maintain an adequate clinical response is reached. Situations that may make dosage adjustments necessary are changes in clinical status secondary to remissions or exacerbations in the disease process, the patient’s individual drug responsiveness, and the effect of patient exposure to stressful situations not directly related to the disease entity under treatment. In this latter situation, it may be necessary to increase the dosage of the corticosteroid for a period of time consistent with the patient’s condition. If after long-term therapy the drug is to be stopped, it is
recommended that it be withdrawn gradually rather than abruptly.

Directions for Use

(1) Shake the foam container vigorously for 5-10 seconds before each use. Do not remove the container cap during use of the product.
(2) Hold the container upright on a level surface and gently place the tip of the applicator onto the nose of the container cap. CONTAINER MUST BE HELD UPRIGHT TO OBTAIN PROPER FLOW OF MEDICATION.
(3) Pull the plunger past the fill line on the applicator barrel.
(4) To fill the applicator barrel, press down firmly on the cap flanges, hold for 1–2 seconds and release. Pause 5–10 seconds to allow foam to expand in the applicator barrel. Repeat until foam reaches fill line. Remove applicator from the container cap. Allow some foam to remain on the applicator tip. A burst of air may come out of the container with the first pump.
(5) Hold the applicator firmly by the barrel, making sure that the thumb and middle finger are positioned securely underneath and resting against the barrel wings. Place the index finger over the plunger. Gently insert applicator tip into anus. Once in place, push the plunger to expel foam, then withdraw applicator.
CAUTION: Do not insert any part of the aerosol container directly into the anus. Apply foam to anus only with enclosed applicator.
(6) After each use, the applicator parts should be pulled apart for thorough cleaning with warm water. The container cap and underlying tip should also be pulled apart and rinsed to help prevent build-up of foam and possible blockage.

Contraindications

ENTOFOAM should not be used if there is a known hypersensitivity to hydrocortisone or to any components of this product.
Local contraindications to the use of intrarectal steroids include obstruction, abscess, perforation, peritonitis, fresh intestinal anastomoses, extensive fistulas, sinus tracts and tuberculous, fungal or viral infections.

Warnings And Precautions

General Precautions

Do not insert any part of the aerosol container directly into the anus. Contents of the container are under pressure. Do not burn or puncture the aerosol container. Do not store at temperatures above 120°F. Because ENTOFOAM is not expelled, systemic hydrocortisone absorption may be greater from ENTOFOAM than from corticosteroid enema formulations. If there is no evidence of clinical or proctologic improvement within 2 or 3 weeks after starting ENTOFOAM therapy, or if the patient’s condition worsens, discontinue the drug. Rare instances of anaphylactoid reactions have occurred in patients receiving corticosteroid therapy.
The lowest possible dose of corticosteroid should be used to control the condition under treatment. When reduction in dosage is possible, the reduction should be gradual.
Since complications of treatment with glucocorticoids are dependent on the size of the dose and the duration of treatment, a risk/benefit decision must be made in each individual case as to the dose and duration of treatment and as to whether daily or intermittent therapy should be used.
Kaposi’s sarcoma has been reported to occur in patients receiving corticosteroid therapy, most often for chronic conditions. Discontinuation of corticosteroids may result in clinical improvement.
General precautions common to all corticosteroid therapy should be observed during treatment with ENTOFOAM, especially in the case of young children. Treatment should be administered with caution in patients with severe ulcerative disease because of their predisposition to perforation of the bowel wall. Although uncommon at this dosage, local irritation may occur.

Patients and/or carers should be warned that potentially severe psychiatric adverse reactions may occur with systemic steroids. Symptoms typically emerge within a few days or weeks of starting the treatment. Risks may be higher with high doses/systemic exposure, although dose levels do not allow prediction of the onset, type, severity or duration of reactions. Most reactions recover after either dose reduction or withdrawal, although specific treatment may be necessary. Patients/carers should be encouraged to seek medical advice if worrying psychological symptoms develop, especially if depressed mood or suicidal ideation is suspected. Patients/carers should also be alert to possible psychiatric disturbances that may occur during or immediately after dose tapering/withdrawal of systemic steroids, although such reactions have been reported infrequently.

Particular care is required when considering the use of systemic corticosteroids in patients with existing or previous history of severe affective disorders in themselves or in their first degree relatives. These would include depressive or manic-depressive illness and previous steroid psychosis.

Cardio-renal
As sodium retention with resultant edema and potassium loss may occur in patients receiving corticosteroids, these agents should be used with caution in patients with congestive heart failure, hypertension, or renal insufficiency.

Endocrine
Drug-induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy; therefore, in any situation of stress occurring during that period, hormone therapy should be reinstituted. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently.

Gastrointestinal
Steroids should be used with caution in active or latent peptic ulcers, diverticulitis, fresh intestinal anastomoses, and nonspecific ulcerative colitis, since they may increase the risk of a perforation. Where surgery is imminent, it is hazardous to wait more than a few days for a satisfactory response to medical treatment.

Do not employ in the immediate or early post-operative period following ileorectostomy.

Signs of peritoneal irritation following gastrointestinal perforation in patients receiving corticosteroids may be minimal or absent.

There is an enhanced effect of corticosteroids in patients with cirrhosis.

Musculoskeletal
Corticosteroids decrease bone formation and increase bone resorption both through their effect on calcium regulation (i.e., decreasing absorption and increasing excretion) and inhibition of osteoblast function. This, together with a decrease in the protein matrix of the bone secondary to an increase in protein catabolism, and reduced sex hormone production, may lead to inhibition of bone growth in pediatric patients and the development of osteoporosis at any age. Special consideration should be given to patients at increased risk of osteoporosis (i.e., postmenopausal women) before initiating corticosteroid therapy.

Neuro-psychiatric
An acute myopathy has been observed with the use of high doses of corticosteroids, most often occurring in patients with disorders of neuromuscular transmission (e.g., myasthenia gravis), or in patients receiving concomitant therapy with neuromuscular blocking drugs (e.g., pancuronium). This acute myopathy is generalized, may involve ocular and
respiratory muscles, and may result in quadriplegia. Elevation of creatinine kinase may occur. Clinical improvement or recovery after stopping corticosteroids may require weeks to years.

Psychic derangements may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.

**Ophthalmic**

Intraocular pressure may become elevated in some individuals. If steroid therapy is continued for more than 6 weeks, intraocular pressure should be monitored.

**Infections**

**General**

Patients who are on corticosteroids are more susceptible to infections than are healthy individuals. There may be decreased resistance and inability to localize infection when corticosteroids are used. Infection with any pathogen (viral, bacterial, fungal, protozoan or helminthic) in any location of the body may be associated with the use of corticosteroids alone or in combination with other immunosuppressive agents. These infections may be mild to severe. With increasing doses of corticosteroids, the rate of occurrence of infectious complications increases. Corticosteroids may also mask some signs of current infection.

**Fungal infections**

Corticosteroids may exacerbate systemic fungal infections and, therefore, should not be used in the presence of such infections unless they are needed to control drug reactions. There have been cases reported in which concomitant use of amphotericin B and hydrocortisone was followed by cardiac enlargement and congestive heart failure.

**Special pathogens**

Latent disease may be activated or there may be an exacerbation of intercurrent infections due to pathogens, including those caused by *Amoeba, Candida, Cryptococcus, Mycobacterium, Nocardia, Pneumocystis*, and *Toxoplasma*.

It is recommended that latent amebiasis or active amebiasis be ruled out before initiating corticosteroid therapy in any patient who has spent time in the tropics or in any patient with unexplained diarrhea.

Similarly, corticosteroids should be used with great care in patients with known or suspected *Strongyloides* (threadworm) infestation. In such patients, corticosteroid-induced immunosuppression may lead to *Strongyloides* hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicemia.

Corticosteroids should not be used in cerebral malaria.

**Tuberculous**

If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary as reactivation of the disease may occur. During prolonged corticosteroid therapy, these patients should receive chemoprophylaxis.

**Vaccination**

Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of corticosteroids. Killed or inactivated vaccines may be administered. However, the response to such vaccines cannot be predicted. Immunization procedures may be undertaken in patients who are receiving corticosteroids as replacement therapy, e.g., for Addison's disease.

**Viral infections**

Chicken pox and measles can have a more serious or even fatal course in pediatric and adult patients on corticosteroids. In pediatric and adult patients who have not had these diseases, particular care should be taken to avoid exposure. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If exposed to chicken pox, prophylaxis with varicella zoster immune globulin may be indicated. If exposed to measles, prophylaxis with
immunoglobulin may be indicated. (See the respective package inserts for complete prescribing information). If chicken pox develops, treatment with antiviral agents should be considered.

**Ophthalmic**

Use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. The use of oral corticosteroids is not recommended in the treatment of optic neuritis and may lead to an increase in the risk of new episodes. Corticosteroids should not be used in active ocular herpes simplex.

**Drug Interactions**

*Aminoglutethimide*: Aminoglutethimide may lead to a loss of corticosteroid-induced adrenal suppression.

*Ampotericin B Injection and Potassium-Depleting Agents*: When corticosteroids are administered concomitantly with potassium-depleting agents (i.e., amphotericin B, diuretics), patients should be observed closely for development of hypokalemia. There have been cases reported in which concomitant use of amphotericin B and hydrocortisone was followed by cardiac enlargement and congestive heart failure.

*Antibiotics*: Macrolide antibiotics have been reported to cause a significant decrease in corticosteroid clearance.

*Anticholinesterases*: Concomitant use of anticholinesterase agents and corticosteroids may produce severe weakness in patients with myasthenia gravis. If possible, anticholinesterase agents should be withdrawn at least 24 hours before initiating corticosteroid therapy.

*Anticoagulants, oral*: Co-administration of corticosteroids and warfarin result in inhibition of response to warfarin. Therefore, coagulation indices should be monitored to maintain the desired anticoagulant effect.

*Antidiabetics*: Because corticosteroids may increase blood glucose concentrations, dosage adjustments of antidiabetic agents may be required.

*Antitubercular drugs*: Serum concentrations of isoniazid may be decreased.

*Cholestyramine*: Cholestyramine may increase the clearance of corticosteroids.

*Cyclosporine*: Increased activity of both cyclosporine and corticosteroids may occur when the two are used concurrently. Convulsions have been reported with this concurrent use.

*Digitalis glycosides*: Patients on digitalis glycosides may be at increased risk of arrhythmias due to hypokalemia.

*Estrogens, including oral contraceptives*: Estrogens may decrease the hepatic metabolism of certain corticosteroids, thereby increasing their effect.

*Hepatic Enzyme Inducers* (e.g., barbiturates, phenytoin, carbamazepine, rifampin): Drugs that induce hepatic microsomal drug metabolizing enzyme activity may enhance the metabolism of corticosteroids and require that the dosage of the corticosteroid be increased.

*Ketoconazole*: Ketoconazole has been reported to decrease the metabolism of certain corticosteroids by up to 60%, leading to an increased risk of corticosteroid side effects.

*Nonsteroidal anti-inflammatory agents (NSAIDS)*: Concomitant use of aspirin (or other NSAIDs) and corticosteroids increases the risk of gastrointestinal side effects. Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia. The clearance of salicylates may be increased with concurrent use of corticosteroids.

*Skin tests*: Corticosteroids may suppress reactions to skin tests.

*Vaccines*: Patients on prolonged corticosteroid therapy may exhibit a diminished response to toxoids and live or inactivated vaccines due to inhibition of antibody response. Corticosteroids may also potentiate the replication of some organisms contained in live attenuated vaccines. Routine administration of vaccines or toxoids should be deferred until corticosteroid therapy is discontinued if possible.

**Information for Patients**
Patients should be warned not to discontinue the use of corticosteroids abruptly or without medical supervision, to advise any medical attendants that they are taking corticosteroids and to seek medical advice at once should they develop fever or other signs of infection.

Persons who are on corticosteroids should be warned to avoid exposure to chicken pox or measles. Patients should also be advised that if they are exposed, medical advice should be sought without delay.

Patients should be encouraged to seek medical advice if worrying psychological symptoms develop, especially if depressed mood or suicidal ideation is suspected. Patients should also be alert to possible psychiatric disturbances that may occur either during or immediately after dose tapering/withdrawal of systemic steroids, although such reactions have been reported infrequently. Particular care is required when considering the use of systemic corticosteroids in patients who have, or whose first-degree relatives have, an existing or previous history of severe affective disorders. These would include depressive or manic-depressive illness and previous steroid psychosis.

**Pregnancy**

*Corticosteroids have been shown to be teratogenic in many species when given in doses equivalent to the human dose. Animal studies in which corticosteroids have been given to pregnant mice, rats, and rabbits have yielded an increased incidence of cleft palate in the offspring. There are no adequate and well-controlled studies in pregnant women. Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have received corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.*

**Lactation**

There are no reports of use of hydrocortisone foam in lactating women. Rectal corticosteroids are not recommended for use by breast-feeding mothers.

**Undesirable Effects**

Although uncommon at this dosage, irritation may occur. Side effects are very unusual with ENTOFOAM, but long term frequent use may cause problems in some people. This is particularly so if the medicine is not used as directed. Although uncommon at this dosage, the following side effects may occur; unexpected fattening of the face, neck and body, periods may stop unexpectedly and hair starts to grow on the face (in women), dusky complexion with purple markings, local irritation.

A wide range of psychiatric reactions including affective disorders (such as irritable, euphoric, depressed and labile mood, and suicidal thoughts), psychotic reactions (including mania, delusions, hallucinations, and aggravation of schizophrenia), behavioral disturbances, irritability, anxiety, sleep disturbances, and cognitive dysfunction including confusion and amnesia have been reported.

Reactions are common and may occur in both adults and children. In adults, the frequency of severe reactions has been estimated to be 5-6%. Psychological effects have been reported on withdrawal of corticosteroids; the frequency is unknown.

**Overdosage**

Treatment of acute overdosage is by supportive and symptomatic therapy. For chronic overdosage in the face of severe disease requiring continuous steroid therapy, the dosage of the corticosteroid may be reduced only temporarily, or alternate day treatment may be introduced.
Shelf Life

24 months from the date of manufacture.

Storage And Handling Instructions

Store below 25° C. Do not refrigerate. Pressurized container contains propellant. Protect from sunlight and do not expose to temperatures above 50°C. Do not pierce or burn even after use.

Packaging Information

ENTOFOAM is supplied in an aerosol can with a special rectal applicator.

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