

PRODUCT MONOGRAPH

Pr Proctofoam-HC[®]

Hydrocortisone Acetate and Pramoxine Hydrochloride Aerosol Foam

Rectal Anti-inflammatory Foam

(DIN 00363014)

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Proctofoam-HC[®]

Hydrocortisone Acetate and Pramoxine Hydrochloride Aerosol Foam

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Rectal. Topical.	aerosol foam / hydrocortisone acetate 1%, pramoxine hydrochloride 1%	Cetyl alcohol, emulsifying wax, isobutane, methylparaben, propane, propylene glycol, propylparaben, steareth-10, triethanolamine and water.

INDICATIONS AND CLINICAL USE

Proctofoam-HC[®] (hydrocortisone acetate 1%, pramoxine hydrochloride 1%) is indicated for the temporary relief of anorectal inflammation, pruritus, pain and swelling associated with hemorrhoids, proctitis, cryptitis, fissures, postoperative pain and pruritus ani.

Geriatrics (> 65 years of age):

Proctofoam-HC[®] should be used cautiously in elderly patients (see **WARNINGS AND PRECAUTIONS** and **DOSAGE AND ADMINISTRATION**).

Pediatrics (< 18 years of age):

Proctofoam-HC[®] has not been studied in the pediatric population. Proctofoam-HC[®] should not be used in children under 18 years of age (see **CONTRAINDICATIONS** and **WARNINGS AND PRECAUTIONS**).

CONTRAINDICATIONS

- Patients with viral (e.g. herpes, varicella or vaccinia) lesions of the skin, bacterial or fungal skin infections, parasitic infections, abscess, extensive fistulas or sinus tracts, skin manifestations relating to tuberculosis or syphilis, eruptions following vaccinations, acne vulgaris, rosacea, pruritus without inflammation.
- Patients who are hypersensitive to hydrocortisone or other corticosteroids, pramoxine, or any non-medicinal component of Proctofoam-HC[®]. See **DOSAGE FORMS, COMPOSITION AND PACKAGING** for the complete listing of ingredients.
- Children (< 18 years of age) (see **WARNINGS AND PRECAUTIONS**).

WARNINGS AND PRECAUTIONS

General

A complete rectal examination should be completed before instituting therapy to rule out serious pathology and assess extension of the disease.

Proctofoam-HC[®] should not be used on infected lesions unless accompanied by anti-infective agents.

If sensitivity develops, therapy with Proctofoam-HC[®] should be discontinued.

Carcinogenesis and Mutagenesis

Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid therapy, most often for chronic conditions. In such cases, discontinuation of the corticosteroid therapy may result in clinical improvement¹.

Cardiovascular

Topical corticosteroids should not be used in patients with stasis dermatitis and other skin conditions with impaired circulation since skin ulceration has occurred in these patients.

Dependence/Tolerance

With repeated administration to the same site, three times daily for 4 to 5 days, tolerance to the anti-inflammatory and vasoconstrictive effects of Proctofoam-HC[®] may occur².

Endocrine and Metabolism

Prolonged use of Proctofoam-HC[®] (hydrocortisone acetate 1%, pramoxine hydrochloride 1%) could produce systemic corticosteroid effects.

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for corticosteroid insufficiency after withdrawal from treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, intertriginous areas (such as the axillae), prolonged use, and the addition of occlusive dressings. Other risk factors for increased systemic effects include increasing hydration of the stratum corneum, use on thin skin areas (such as the face), use on broken skin or conditions where the skin barrier may be impaired.

If HPA axis suppression is noted, an attempt should be made to gradually withdraw the drug reducing the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of corticosteroid insufficiency may occur requiring supplemental systemic corticosteroids. For information on systemic supplementation, see prescribing information for those products.

Patients with acute illness or injury may have increased morbidity and mortality with intermittent HPA axis suppression. Patients should be instructed to use Proctofoam-HC[®] for the minimum amount of time necessary to achieve the desired results (see **DOSAGE AND ADMINISTRATION**).

Hypothyroidism may cause an enhanced effect of corticosteroids.

Gastrointestinal

Proctofoam-HC[®] should be used with caution in patients with severe ulcerative disease, and only after adequate proctologic examination, due to the risk of intestinal perforation.

Hematologic

Caution is advised in patients with hypoprothrombinemia when acetylsalicylic acid (ASA) is used in conjunction with Proctofoam-HC[®].

Hepatic/Biliary/Pancreatic

Reduced clearance, secondary to cirrhosis or severe hepatic impairment, may enhance the corticosteroid effects of Proctofoam-HC[®].

Immune

Proctofoam-HC[®] should be used with caution in patients with impaired T-cell function or in those receiving other immunosuppressive therapy.

Infections may be masked or enhanced and new infections (including secondary bacterial infection) may occur during corticosteroid use due to suppression of the immune response. If concomitant skin infections develop, Proctofoam-HC[®] should be discontinued until the infection has been adequately controlled.

Peri-Operative Considerations

Proctofoam-HC[®] should not be used immediately, or in the early postoperative period, following ileorectostomy.

Psychiatric

Prolonged use of corticosteroids may cause adverse psychiatric reactions including euphoria, mood swings, depression and anxiety, and personality changes to frank psychoses. Caution should be used in psychotic patients as emotional instability or psychotic tendencies may be aggravated².

Sensitivity/Resistance

Allergic contact dermatitis associated with topical corticosteroids is usually diagnosed by observing a failure to heal as opposed to a clinical exacerbation. Such an observation should be corroborated with appropriate diagnostic patch testing.

Local hypersensitivity reactions (see **ADVERSE REACTIONS**) may resemble symptoms of the condition under treatment. If hypersensitivity reactions occur, the drug should be discontinued and appropriate therapy initiated if there are signs of reaction.

Pramoxine's chemical structure is likely to minimize the danger of cross-sensitivity reactions in patients allergic to other local anesthetics.

Skin

If irritation develops, Proctofoam-HC[®] should be discontinued and appropriate therapy instituted. Prolonged use of topical corticosteroid preparations may produce striae or atrophy of the skin or subcutaneous tissue. If skin atrophy is observed, treatment should be discontinued.

Proctofoam-HC[®] should not be applied to extensive areas of skin, open wounds, or damaged/blistered skin.

Special Populations

Pregnant Women:

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. Subcutaneous administration of hydrocortisone to mice at doses ≥ 30 mg/kg/day and rabbits at a dose of $675\mu\text{g}/\text{kg}/\text{day}$ and a single intramuscular injection of ≥ 25 mg to hamsters during pregnancy produced foetal abnormalities including cleft palate.

The relevance of this finding to human beings has not been established; however, there is some data showing an association between use of topical corticosteroids in the first trimester of pregnancy and an increased risk of cleft lip with or without cleft palate (OR=1.45; 95%CI 1.03-2.05). Administration of corticosteroids during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the foetus. The minimum quantity should be used for the minimum duration.

Topical corticosteroids cross the skin barrier and unmetabolized hydrocortisone has been found to cross the placenta³.

Nursing Women:

It is unknown if Proctofoam-HC[®] is excreted in human milk.

The safety of topical corticosteroids during lactation has not been established; however, systemic corticosteroids are known to be distributed into milk.

The molecular weight of pramoxine is low enough for excretion into breast milk but its impact on lactation has not been established⁴.

The potential benefit to the mother should be weighed against possible hazards to the nursing infant.

Pediatrics (<18 years of age):

The safety and effectiveness of Proctofoam-HC[®], or the combination of hydrocortisone acetate-pramoxine hydrochloride, has not been established in the pediatric population. Proctofoam-HC[®] should not be used in children under 18 years of age.

Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during and/or after withdrawal of treatment. Adverse effects including striae have been reported with use of topical corticosteroids in infants and children. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. Chronic corticosteroid therapy may interfere with the growth and development of children.

Geriatrics (> 65 years of age):

Proctofoam-HC[®] should be used cautiously in elderly patients, reflecting their increased skin fragility and greater frequency of hepatic, renal, or cardiac dysfunction, and of concomitant disease or use of other medications.

Monitoring and Laboratory Tests

The cosyntropin (ACTH₁₋₂₄) stimulation test may be helpful in evaluating patients for HPA axis suppression.

ADVERSE REACTIONS**Adverse Drug Reaction Overview**

Patients may experience itching, burning and/or pain upon application of Proctofoam-HC[®] (hydrocortisone acetate 1% and pramoxine hydrochloride 1%). Other reported reactions with pramoxine have included angioedema, contact dermatitis, edema, urticaria, urethritis and tenderness.

The following local adverse reactions have been reported with the use of topical corticosteroids: dryness, itching, burning, local irritation, striae, skin atrophy, hypertrichosis, hypopigmentation, secondary infection, pustules, miliaria, folliculitis and pyoderma may occur.

Adverse effects generally associated with the use of systemic corticosteroids can also occur with the use of topical corticosteroids. Conditions that may increase systemic absorption include use of the more potent steroids, use over a prolonged period of time, use over a large surface area and use with an occlusive dressing.

Systemic absorption of topical corticosteroids has produced reversible suppression of the (HPA)-axis and manifestations of Cushing's syndrome.

Allergic reactions to any ingredients in the formulation may occur.

Clinical Trial Adverse Drug Reactions

Because clinical trials are conducted under very specific conditions the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.

In an investigation by Miller involving 109 patients with anorectal disorders, there were 18 reports of minor side effects such as itching, burning, urge to defecate and pain on insertion, and

three (3) reports of allergic responses. These responses were not unexpected due to the sensitization characteristics of the anorectal area; many therapeutic agents applied to this area result in allergic response⁵. In another study by Lippincott of 92 proctologic patients, three (3) reported a burning sensation from the medication⁶. In a clinical trial by Nenno and Loehfelm, it was shown that the application of Proctofoam-HC[®] to 50 postpartum patients having undergone episiotomies led to rapid healing, with no reports of sensitivity reactions and no complications that could be attributed to the medication⁷. In a report by Lieberman of 100 patients treated with Proctofoam, three (3) experienced burning, one (1) experienced slight itching and another experienced irritation⁸.

Post-Market Adverse Drug Reactions

The following adverse events have been reported during post-marketing experience with Proctofoam-HC[®]: rash, infection, burning, erythema, itching, pain and anal spasm.

DRUG INTERACTIONS

Overview

No formal drug-drug, drug-food, drug-herb or drug-laboratory interaction studies have been performed with Proctofoam-HC[®].

Drug-Drug Interactions

Drug interactions have been reported between systemic corticosteroids and certain classes of drugs such as: anticholinesterase agents, antitubercular drugs, drugs affecting hepatic microsomal enzymes (particularly CYP3A4 inhibitors), antidiabetic therapy, estrogens, nonsteroidal anti-inflammatory agents, potassium-depleting drugs, vaccines and toxoids, and oral anticoagulants².

Co-administered drugs that can inhibit CYP3A4 (e.g., ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

Benzoyl peroxide chemically reacts with topical anesthetics such as pramoxine causing a significant reduction in its numbing effect⁹.

Drug-Food Interactions

Interactions with food have not been established.

Drug-Herb Interactions

Herbs that may have immunostimulant properties such as Cat's claw and Echinacea can potentially diminish the immunosuppressant effect of corticosteroids.

Drug-Laboratory Test Interactions

Corticosteroids may decrease radioactive iodine (I^{131}) uptake and produce false negative results in the nitroblue tetrazolium test for systemic bacterial infection².

Glucocorticoids may suppress reactions to skin tests².

DOSAGE AND ADMINISTRATION

Dosing Considerations

Patients should be instructed to use Proctofoam-HC[®] for the minimum amount of time necessary to achieve the desired results because of the potential for corticosteroids to suppress the hypothalamic-pituitary-adrenal axis and cause skin atrophy (see **WARNINGS AND PRECAUTIONS**). If condition worsens or a symptomatic response is not noted following seven (7) days of treatment, the patient's condition and treatment options should be re-evaluated.

Proctofoam-HC[®] is for rectal use only. It should not be taken by mouth or any other route.

One application contains 375 mg of mucoadhesive base containing 1% hydrocortisone acetate, (3.75 mg/dose) and 1% pramoxine hydrochloride, (3.75 mg/dose).

Recommended Dose and Dosage Adjustment

The aerosol container should be shaken before using.

One applicatorful should be injected into the anus two or three times daily and after bowel evacuation. The foam may also be placed on a perianal pad and applied externally as needed to relieve pain or itching, into the anus, two or three times daily, and after bowel evacuation or as otherwise deemed necessary based on the patient's condition.

When a favourable response is achieved, the therapy should be discontinued.

Pediatrics (<18 years of age):

Proctofoam-HC[®] should not be used in children under 18 years of age.

Geriatrics (>65 years of age):

Topical corticosteroids should be used cautiously in elderly patients. Patients should be instructed to use Proctofoam-HC[®] for the minimum amount of time necessary to achieve the desired results.

Missed Dose

In the event that a dose is missed, it should be taken as soon as possible. However, if it is almost time for the next dose, the missed dose should be skipped. The next dose should not be doubled and the therapy should be continued as per the recommended dosing schedule.

Administration

To ensure adequate administration of the proper dose of the drug, the patient should be instructed by the physician or healthcare professional in the proper use of Proctofoam-HC[®], including whether the product is to be applied rectally or perianally.

The applicator supplied with the medication is strictly for rectal use. The foam can also be applied topically to the perianal area. Fingers or any other device should not be used to administer the foam. Parts of the aerosol container should not be inserted into the anus.

OVERDOSAGE

Overdosage is improbable at the levels of hydrocortisone acetate and pramoxine hydrochloride in one container of Proctofoam-HC[®]. This medicine may be harmful if swallowed. In case of ingestion, symptomatic treatment should be instituted.

However, as excess use of topical corticosteroids may produce systemic adverse effects, in case of chronic overdosage or misuse, the features of hypercorticism may appear.

For management of suspected drug overdose, contact your regional Poison Control Centre.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

Proctofoam-HC[®] (hydrocortisone acetate 1%, pramoxine hydrochloride 1%) is an anti-inflammatory and anti-pruritic with emollient properties that aid in soothing and lubricating the mucosa to make evacuation more comfortable.

Hydrocortisone acetate has anti-inflammatory, anti-pruritic, and vasoconstrictive properties. Though the mechanism of the anti-inflammatory activity of topical corticosteroids is generally unclear, corticosteroids are thought to induce phospholipase A2 inhibitor proteins, preventing arachidonic acid release and the biosynthesis of potent mediators of inflammation¹⁰.

Pramoxine hydrochloride 1% is a surface or local anesthetic, which is not chemically related to the “cain” types of local anesthetics. Its unique chemical structure is likely to minimize the danger of cross-sensitivity reactions in patients allergic to other local anesthetics¹¹. Pramoxine works by interfering with pain signals sent from the nerves to the brain.

Pharmacodynamics

Pharmacodynamic studies have not been conducted with Proctofoam-HC[®].

The anti-inflammatory action of hydrocortisone is palliative, not curative. Hydrocortisone acetate inhibits the inflammatory reaction to toxic or mechanical injuries. It has a slow onset of action and a long duration of therapeutic action. The maximal effect of topical corticosteroids may take 2 to 3 days to achieve.

The anesthetic effects of pramoxine are immediate; typically apparent within 2 to 5 minutes. Therapeutic action will last up to five (5) hours depending on the amount applied².

Pharmacokinetics

No pharmacokinetics studies have been conducted with Proctofoam-HC[®].

Absorption:

Topical corticosteroids can be absorbed from normal skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption. Moreover, continued absorption of corticosteroids may occur, even after washing, due to retention of the drug in the stratum corneum.

Topical application of corticosteroids to the mucosa of the genitourinary or lower intestinal tract may result in substantial systemic absorption of the medications. In healthy individuals, as much as 30-90% of rectally administered hydrocortisone as a retention enema may be absorbed (with a mean absolute bioavailability of approximately 3% to 4.5%¹⁴). Greater amounts of hydrocortisone may be absorbed rectally if the intestinal mucosa is inflamed. Cortisol (hydrocortisone) is bound primarily to transcortin and only 5-10% of cortisol in plasma is unbound and is biologically active². Following percutaneous penetration of a topical corticosteroid, the drug that is systemically absorbed probably follows the metabolic pathways of systemically administered corticosteroids.

The absorption amount of pramoxine after topical administration into the systemic circulation is unknown.

Distribution:

Animal studies indicate that most corticosteroids are rapidly removed from the blood and distributed to muscles, liver, skin, intestines, and kidneys.

Data on pramoxine distribution is not available.

Metabolism:

Corticosteroids are usually metabolized in the liver. The half-life ($t_{1/2}$) of hydrocortisone is approximately 1.7 ± 0.2 hours following intravenous administration¹².

Data on pramoxine metabolism is not available.

Excretion:

Corticosteroids are usually excreted by the kidneys.

Data on pramoxine excretion is not available.

Special Populations and Conditions**Hepatic Insufficiency:**

In the event of systemic absorption; metabolism and elimination may be delayed in patients with hepatic impairment leading to increased risk of systemic toxicity.

Renal Insufficiency:

In the event of systemic absorption; metabolism and elimination may be delayed in patients with renal impairment leading to increased risk of systemic toxicity.

STORAGE AND STABILITY

Store and use at room temperature (15 - 30°C).

Store in an upright position and in original packaging to protect from sunlight.

Do not use Proctofoam-HC[®] after the expiry date printed on the aerosol container and carton. The expiry date refers to the last day of that month inclusively.

Keep out of reach of children and pets.

SPECIAL HANDLING INSTRUCTIONS

Do not puncture or incinerate the aerosol container.

Contents of the aerosol container are under pressure and are flammable. The aerosol container may explode if heated. Do not use in the presence of an open flame or spark. Do not place the aerosol container in hot water or near radiators, stoves or other sources of heat. Do not refrigerate.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Proctofoam-HC[®] is supplied in an aerosol container with both an internal and external cap as well as an applicator. Each application delivers approximately 375 mg of foam containing approximately 1% hydrocortisone acetate (3.75 mg/dose) and 1% pramoxine hydrochloride (3.75 mg/dose). The 22.4g aerosol container will deliver approximately 36 applications.

It also contains cetyl alcohol, emulsifying wax, isobutane, methylparaben, propane, propylene glycol, propylparaben, steareth-10, triethanolamine and water.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

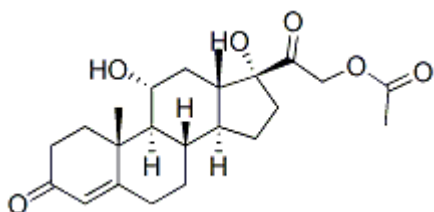
Drug Substance

Proper name: Hydrocortisone acetate

Chemical name: Cortisol 21-acetate

Molecular formula and molecular mass: $C_{23}H_{32}O_6$
404.5

Structural formula:



Physicochemical properties: White to practically white, odourless crystalline powder; insoluble in water, slightly soluble in alcohol and chloroform. Melts at 220°C.

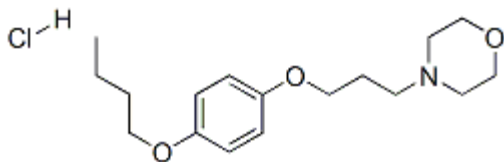
Drug Substance

Proper name: Pramoxine hydrochloride

Chemical name: 4-[3-(p-Butoxyphenoxy) propyl] morpholine hydrochloride

Molecular formula and molecular mass: $C_{17}H_{27}NO_3HCl$
329.87

Structural formula:



Physicochemical properties: White to nearly white crystalline powder with a numbing taste; freely soluble in alcohol and water, soluble in chloroform and slightly soluble in ether. Melts between 170°C and 174°C.

DETAILED PHARMACOLOGY

Tromm et al. determined the pharmacokinetics and bioavailability of hydrocortisone (100 mg) after rectal administration of hydrocortisone acetate foam following single and multiple rectal dosing in eight (8) healthy volunteers and in eight (8) patients with inflammatory bowel disease. Endogenous hydrocortisone was suppressed by dexamethasone administration and plasma levels were compared with those observed after intravenous administration of hydrocortisone. Only a small fraction of the administered rectal doses was absorbed. The mean absolute bioavailability was 3.1% in healthy subjects and 4.5% in patients. Substantial intersubject variability was noted. Although maximum hydrocortisone levels after single or multiple doses were significantly higher in the patient group, the systemic bioavailability is very low; thus, making hydrocortisone acetate foam a very safe and suitable dosage form for the local treatment of chronic inflammatory bowel diseases¹².

The purpose of Petitjean et al.'s study was to estimate the bioavailability of hydrocortisone (60 mg) after rectal administration of hydrocortisone acetate foam in eight (8) healthy volunteers and in eight (8) patients with an inflamed rectum [idiopathic ulcerative colitis (4 patients) and X-irradiation colitis (4 patients)]. Dexamethasone was given to suppress endogenous hydrocortisone during the study. After rectal administration of hydrocortisone acetate foam to healthy volunteers, the plasma levels were low (plasma hydrocortisone levels were in the physiological range); the mean bioavailability was 30.0%. When hydrocortisone acetate foam was administered to patients, the mean bioavailability was reduced to 16.4%; this decrease was not statistically significant. There was also a non-significant tendency to faster absorption of hydrocortisone in patients vs. healthy volunteers. These results suggest that the local inflammatory process can reduce the absorption of hydrocortisone when compared to healthy volunteers¹³.

TOXICOLOGY

No toxicological studies have been conducted with Proctofoam-HC[®] or with pramoxine hydrochloride alone. However, such studies are available for corticosteroids.

Multiple studies described the effects of cortisone, or hydrocortisone, on the pregnancy outcomes in animals. When pregnant mice were administered cortisone intra-muscularly, doses ranging from 0.625-10 mg for an average of 4-5 days, a dose-related incidence of cleft palate and litter resorption were observed. Moreover, cleft palate and cataract were frequently observed in the offspring of pregnant mice (weight 20g) that were administered 1mg of hydrocortisone subcutaneously for 2-4 days during the second half of the gestation. Topical administration of corticosteroids to pregnant animals can cause abnormalities in fetal development.

A study demonstrated that a 250 mg/kg/day subcutaneous dose of hydrocortisone in pregnant mice on gestational days 11 through 17 could also induce polycystic kidney disease in the fetus.

When intramuscular injection of cortisone doses, ranging from 1-8 mg/kg/day, were administered

to pregnant rabbits, gross congenital anomalies were not seen in the offspring; however, cleft palate, intra-uterine growth restriction, and increased neonatal death were observed⁴.

Sexual Function/Reproduction

Corticosteroids have been shown to increase or decrease motility and number of spermatozoa in some men. It is not known whether topical corticosteroids affect fertility. However, reproduction studies in rats using subcutaneous dosages of clobetasol propionate up to 50mcg/kg daily have revealed an increase in the incidence of fetal resorption and a decrease in the number of living fetuses at the highest dose².

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PART III: CONSUMER INFORMATION

Proctofoam-HC[®]

Hydrocortisone Acetate and Pramoxine Hydrochloride Aerosol Foam

This leaflet is part III of a three-part "Product Monograph" and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Proctofoam-HC[®]. Contact your doctor or pharmacist if you have any questions about the medication.

ABOUT THIS MEDICATION

What the medication is used for:

Proctofoam-HC[®] is used to temporarily relieve inflammation, itchiness, pain and swelling caused by hemorrhoids, proctitis, cryptitis, fissures, postoperative pain and pruritus ani of the rectal and anal area.

What it does:

Proctofoam-HC[®] contains two ingredients: hydrocortisone acetate helps reduce swelling, itchiness, and redness; pramoxine hydrochloride temporarily numbs the area and helps relieve pain and itching.

When it should not be used:

Proctofoam-HC[®] should not be used if you:

- have an infection, ano-rectal abscess or abnormal duct/passage (extensive fistulas or sinus tracts), skin manifestations relating to tuberculosis, parasitic infections, acne, rosacea, itching without inflammation.
- are hypersensitive to hydrocortisone or other corticosteroids, pramoxine, or any non-medicinal component of Proctofoam-HC[®].
- Proctofoam-HC[®] should not be used in children under 18 years of age.

What the medicinal ingredients are:

Proctofoam-HC[®] contains hydrocortisone acetate 1% and pramoxine hydrochloride 1%.

What the non-medicinal ingredients are:

Proctofoam-HC[®] also contains cetyl alcohol, emulsifying wax, isobutane, methylparaben, propane, propylene glycol, propylparaben, steareth-10, triethanolamine and water.

What dosage forms it comes in:

Proctofoam-HC[®] is supplied in an aerosol container with both an internal and external cap as well as an applicator. Each application delivers approximately 375 mg of foam which contains approximately 1% hydrocortisone acetate (3.75 mg/dose) and 1% pramoxine hydrochloride (3.75 mg/dose).

WARNINGS AND PRECAUTIONS

Avoid Proctofoam-HC[®] foam from getting into the eyes, nose and ears. Prolonged use of Proctofoam-HC[®] may cause Cushing's syndrome (weight gain, rounding of the face and/or abnormal hair growth, thinning of the skin).

BEFORE you use Proctofoam-HC[®] talk to your doctor or pharmacist if you:

- have low thyroid function;
- have severe rectal or intestinal ulcers;
- have blood clotting problem (prothrombin deficiency);
- have venous insufficiency that causes skin sore or ulcer in the lower leg (stasis dermatitis and ulcers)
- have liver disease or severe liver impairment;
- have low immune system (e.g. impaired T-cell function, immunosuppressive therapy);
- are suffering or have suffered from psychotic tendencies or emotional instabilities;
- are pregnant, trying to become pregnant or breastfeeding; or
- just had an ileorectostomy.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor, pharmacist or healthcare professional if you are taking any other drugs, including prescription, non-prescription or natural health products, as well as herbal and alternative medicines since drug interactions can affect how Proctofoam-HC[®] works and may increase the risk of side effects.

Drugs that may interact with Proctofoam-HC[®] include:

- drugs to treat Alzheimer's disease,
- blood thinning drugs (such as warfarin)
- drugs for high blood sugar (diabetes)
- drugs for tuberculosis;
- water pills (diuretics);
- drugs affecting hepatic microsomal enzymes [including HIV medicines, some macrolide antibiotics, drugs to treat fungal infections, and some medications used to treat hypertension and angina (e.g. calcium channel blockers)];
- products containing benzoyl peroxide as these products may reduce numbing effect of pramoxine hydrochloride;
- hormones (such as estrogen)
- nonsteroidal anti-inflammatory agents such as ibuprofen and aspirin
- vaccines

PROPER USE OF THIS MEDICATION

Proctofoam-HC[®] is for anal and rectal use only. Do not take it by mouth or by any other route. This medication may be harmful if swallowed.

Proctofoam-HC[®] should be taken as prescribed by your doctor. Talk to your doctor if your condition worsens or is not getting any better after 7 days of treatment.

Do not use Proctofoam-HC[®] after the expiry date which is printed on the canister. The expiry date refers to the last day of that month inclusively.

Usual dose:

One applicatorful into the anus two or three times daily and after bowel evacuation. The foam may also be placed on a pad or gauze and applied externally to relieve pain or itching.

CAUTION:

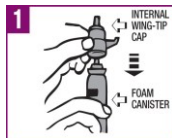
- The applicator supplied with the medication is for anal use only. Never insert canister, internal or external cap into the anus.
- Fingers or any other device should not be used to administer the foam.
- Wash your hands before and after each application.

Please read the directions for internal and external use carefully before you use Proctofoam-HC[®].

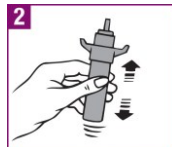
DIRECTIONS FOR INTERNAL USE

If possible, clean and pat dry the affected area before using the product.

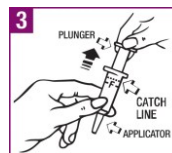
Ensure **that internal wing-tip cap** has been placed on canister (Picture 1).



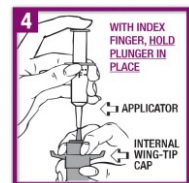
Hold canister in an upright position and shake vigorously for 20-30 seconds (Picture 2).



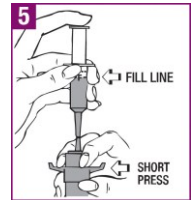
Withdraw plunger **slowly** until it stops at the catch line. This is the dotted line near the top of the applicator barrel (see diagram). It is **not** the fill line (Picture 3).



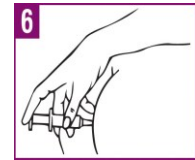
Hold applicator by barrel. **With index finger, hold plunger in place** (see diagram). Holding the canister in an **upright position**, place applicator tip over wing-tip cap and push down gently so that applicator is firmly attached (Picture 4).



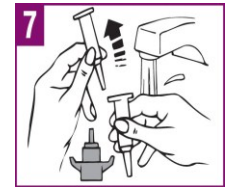
Press down gently on the wings of the internal cap to release the foam. Only a short press is needed to do this. If required, repeat until foam reaches the **fill line** (Picture 5).



Remove applicator from wing-tip cap, leaving some foam on applicator tip. Hold applicator by barrel and gently insert applicator tip into the anus and then push plunger to release foam and complete treatment (Picture 6).



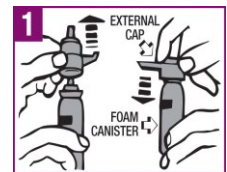
To clean, pull applicator and plunger apart and wash with warm tap water after each use. The wing-tip cap should be removed from the canister. The wing-tip cap and stem rising from the canister should be rinsed with warm tap water after each use. Ensure all parts are gently dried with a clean cloth (Picture 7).



DIRECTIONS FOR EXTERNAL USE

If possible, clean and pat dry the affected area before using the product.

Remove **internal wing-tip cap** from canister. Replace with **external cap**. Take special care not to crush the stem rising from the canister when changing caps (Picture 1).



Hold canister in an **upright position** and shake vigorously for 20-30 seconds (Picture 2).



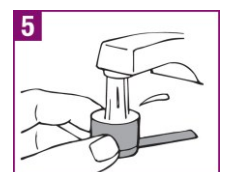
Holding the canister in an upright position, dispense foam onto a pad or gauze by pushing gently down on external canister cap with fingers. Only a short press is needed to do this. Repeat as required (Picture 3).



Apply to affected area as indicated by your doctor (Picture 4).



To clean, the external cap should be removed from the canister. The external cap and stem rising from the canister should be rinsed with warm tap water after each use. Ensure all parts are gently dried with a clean cloth (Picture 5).



Overdose:

In case of drug overdose or accidental ingestion, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

In the event that a dose is missed, you should take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and continue the prescribed dosing schedule; do not double the next dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects with the use of Proctofoam-HC® include:

- itching
- burning
- pain upon application
- dryness,
- irritation, thinning of the skin,
- abnormal hair growth,
- loss of skin color (hypopigmentation),
- secondary infection
- stinging, skin swelling

Prolonged use of Proctofoam-HC® could cause systemic corticosteroid effects which may include Cushing's syndrome (weight gain, rounding of the face and/or abnormal hair growth). Other possible side effects may include increased sugar levels in your blood or urine, high blood pressure, cloudy lens in the eye, increased pressure in the eye and weakening of the bones through gradual mineral loss.

You should talk to your doctor or pharmacist if you have any signs of local or systemic side effects.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist immediately
	Only if severe	In all cases	
Allergic Reaction			X
Cushing's syndrome (weight gain, rounding of the face and/or abnormal hair growth, thinning of the skin)			X
High blood sugar (Hyperglycemia)		X	
Increased sugar levels in your urine (Glucosuria)		X	
High blood pressure (Hypertension)		X	

This is not a complete list of side effects. For any unexpected effects while taking Proctofoam-HC®, contact your doctor or pharmacist.

HOW TO STORE IT

- Store upright and use at room temperature (15-30°C).
- Keep out of reach of children.
- Do not use in the presence of an open flame or spark.
- Do not puncture or incinerate the aerosol container.
- Contents of the aerosol container are under pressure and are flammable. The aerosol container may explode if heated.
- Do not place the aerosol container in hot water or near radiators, stoves or other sources of heat.
- Do not refrigerate.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at www.healthcanada.gc.ca/medeffect
Call toll-free at 1-866-234-2345

Complete a Canada Vigilance Reporting Form and:

- Fax toll-free to 1-866-678-6789, or

- Mail to: **Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

You may need to read this leaflet again. Please do not throw it away until you have finished your medicine.

This document plus the full product monograph, prepared for healthcare professionals can be found by contacting the sponsor, Duchesnay Inc. at:
950, boul. Michèle-Bohec
Blainville, Québec, Canada
J7C 5E2
Tel: 1-888-666-0611
Fax: 1-888-588-8508
www.duchesnay.com
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