

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.

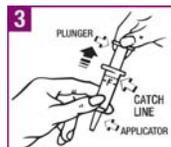
Ensure that **internal wing-tip cap** has been placed on canister (Picture 1).



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



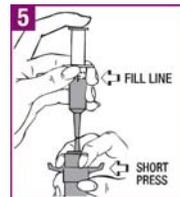
Withdraw plunger **slowly** until it stops at the catch line. This is the dotted line near the top of the applicator barrel (see diagram). It is **not** the fill line (Picture 3).



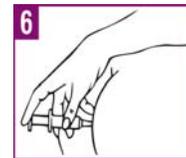
Hold applicator by barrel. **With index finger, hold plunger in place** (see diagram). Holding the canister in an **upright position**, place applicator tip over wing-tip cap and push down gently so that applicator is firmly attached (Picture 4).



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).



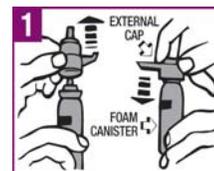
To clean, pull applicator and plunger apart and wash with warm tap water after each use. The wing-tip cap should be removed from the canister. The wing-tip cap and stem rising from the canister should be rinsed with warm tap water after each use. Ensure all parts are gently dried with a clean cloth (Picture 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.
- 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 store at temperature over 50°C.
- 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 Michèle-Bohec Blvd.

Blainville, Quebec, Canada

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Tel: 1-888-666-0611

Fax: 1-888-588-8508

www.duchesnay.com

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