

## Patient Information Leaflet

### Proctofoam HC

#### 1% w/w & 1%w/w Rectal Foam

(Hydrocortisone acetate / pramocaine hydrochloride)

#### Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine had been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- Throughout this leaflet Proctofoam HC 1% w/w & 1% w/w Rectal Foam is called Proctofoam.

#### Important:

- **Proctofoam is a steroid medicine**, prescribed for many different conditions, including serious illness
- **You need to use it regularly** to get the maximum benefit
- **Don't stop using this medicine** without talking to your doctor – you may need to reduce the dose gradually
- **Proctofoam can cause side effects in some people** (read section 4). Some problems such as mood changes (feeling depressed, or 'high'), or stomach problems can happen straight away. If you feel unwell in any way, keep using your medicine, but **see your doctor straight away**
- **Some side effects only happen after weeks or months.** These include weakness of arms and legs, or developing a rounder face (read section 4 for more information)
- **Keep away from people who have chicken-pox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chicken-pox or shingles, **see your doctor straight away**.

#### In this leaflet:

1. What Proctofoam is and what it is used for
2. What you need to know before you use Proctofoam
3. How to use Proctofoam
4. Possible side effects
5. How to store Proctofoam
6. Contents of the pack and other information

#### 1. WHAT PROCTOFOAM IS AND WHAT IT IS USED FOR

##### Proctofoam – benefit information

Proctofoam belongs to a group of medicines called steroids. Their full name is corticosteroids. These corticosteroids occur naturally in the body, and help to maintain health and well-being. Boosting your body with extra corticosteroids (such as Proctofoam) is an effective way to treat various illnesses involving inflammation in the body.

Proctofoam reduces the inflammation, which could otherwise go on making your condition worse. You must use this medicine regularly to get maximum benefit from it. Proctofoam is used for the relief of inflammation, itching, pain, swelling and irritation associated with haemorrhoids (piles) and certain other conditions of the anus (bottom) and anal region.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU USE PROCTOFOAM

### Do not use Proctofoam:

- If you are allergic to pramocaine hydrochloride or to any other ingredient in Proctofoam (see section 6)
- If you are suffering from a bacterial infection, viral infection or fungal infection

### Check with your doctor first:

- **If you have ever had severe depression** or manic-depression (bipolar disorder). This includes having had depression before while using steroid medicines like Proctofoam.
- **If any of your close family** has had these illnesses
- If you have diseases of the bowel (rectum)

### Warnings and Precautions

Contact your doctor if you experience blurred vision or other visual disturbances.

Corticosteroids can cause a rise in blood pressure, salt and water retention in the blood and increased urinary excretion of potassium. Therefore, patients with severe cardiac and/or renal insufficiency will require careful monitoring, and in patients with hypertension, regular blood pressure control is necessary.

Patients should not be vaccinated with live vaccine while on therapy of corticosteroids.

Glucocorticoids can lead to positive results in doping tests.

Children

Proctofoam is not for use in children

### Other medicines and Proctofoam

Tell your doctor or pharmacist if you are taking or have recently taken, or might take any other medicines.. Some medicines may increase the effects of Proctofoam and your doctor may wish to monitor you carefully if you are taking these medicines, including some medicines for HIV e.g. ritonavir, cobicistat, salicylates and other NSAIDs, potassium depleting agents, coumarin derivatives, cardiac glycosides, CYP3A inhibitors.

### Pregnancy and breast-feeding

If you are pregnant, trying to become pregnant or breast-feeding ask your doctor or pharmacist for advice before using Proctofoam.

### Driving and using machines

Proctofoam has no influence on the ability to drive and use machines.

### Excipients Warnings

Proctofoam contains cetyl and cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis). Proctofoam also contains methyl parahydroxybenzoate (E216) and propyl parahydroxybenzoates (E218) which may cause allergic reactions (possibly delayed),

and exceptionally, bronchospasm. This product also contains propylene glycol which may cause skin irritation.

### 3. HOW TO USE PROCTOFOAM

Always use Proctofoam exactly as your doctor has told you.

#### **Important:**

**Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it is not, or you are not sure, ask your doctor or pharmacist.**

#### **Remember:**

- Do not use Proctofoam for more than 7 days
- Talk to your doctor if symptoms worsen, or do not improve within 7 days or if bleeding occurs
- You need to use your medicine regularly to get the maximum benefit.

#### **Adult dose**

Proctofoam can be applied in the rectum (internal use) or to the skin around the anus (external use).

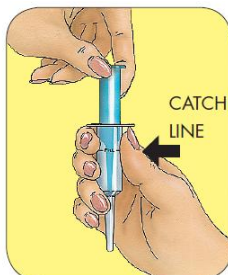
- The usual dose into the rectum is one applicator of foam two or three times per day and after each bowel evacuation up to a maximum of 4 times daily
- For the anal area expel a small amount of foam onto two fingers and apply the affected area.

#### **For internal use**

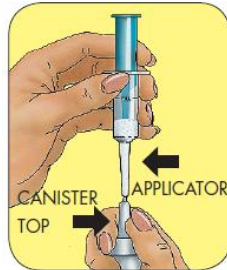
1. Shake the canister vigorously for 30 seconds before each use.



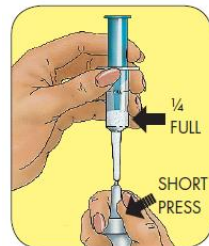
2. Withdraw the plunger to catch the mechanism approx. ½ cm above the fill line.



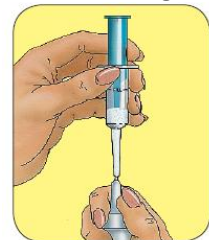
3. Hold the applicator UPRIGHT and insert the canister top into the applicator tip. Make sure you hold the plunger and applicator body FIRMLY with your fingers.



4. Press down a number of times on the canister top with your fingers. Each press releases a small amount of foam. When the applicator is half full of foam, stop for a few seconds until the foam stops expanding.

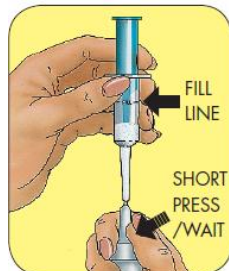


5. Press down again to complete filling the fill line



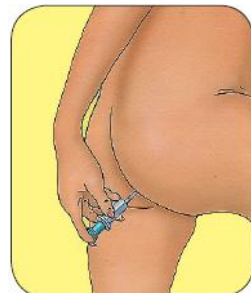
**6. For internal use**

Stand with one leg raised on a chair or lie down on your side. Hold as shown. Insert gently into the back passage and push the plunger fully into the applicator.



**7. For external use.**

Expel a small amount of foam onto a tissue, pad or two fingers and apply the foam to the affected area.



**For topical use**

Shake the canister vigorously for 30 seconds before each use. Expel a small quantity of foam onto a tissue, pad or two fingers and apply the foam to the affected area.

**After using the applicator**

- Always take the applicator apart and wash it thoroughly after use
- The canister top should also be removed and washed
- Replace the canister top with care. Make sure it is placed vertically on top of the canister, and not at an angle.

**If you use more Proctofoam than you should**

If you use too much go to your doctor as soon as possible.

If you repeatedly use too much Proctofoam you may experience fattening of the face, neck and body, hair and growing on your body (women), a dusky complexion with purple patches and skin thinning.

**If you forget to use Proctofoam**

Do not use double the dose to make up for a missed dose. Simply take your next dose as planned.

**If you stop using Proctofoam**

Do not stop using Proctofoam without talking to your doctor. Your doctor may reduce your dose gradually.

**Mental problems while using Proctofoam**

Mental health problems can happen while using steroids like Proctofoam (see also section 4 Possible Side Effects).

- These illnesses can be serious
- Usually they start within a few days or weeks of starting the medicine.
- They are more likely to happen at high doses.
- Most of these problems go away if the dose is lowered or the medicine is stopped. However, if problems do happen they might need treatment.

Talk to a doctor if you (or someone using this medicine), show any signs of mental problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Proctofoam can cause side effects, although not everybody gets them.

Very common ( $\geq 1/10$ )

Common ( $\geq 1/100$  to  $< 1/10$ )

Uncommon ( $\geq 1/1,000$  to  $< 1/100$ )

Rare ( $\geq 1/10,000$  to  $< 1/1,000$ )

Very rare ( $< 1/10,000$ )

Not known (cannot be estimated from the available data)

**Immune system disorders:**

Not known: Hypersensitivity including anaphylactic reaction, angioedema,

**Eye disorders:**

Not known: Blurred vision

**Gastrointestinal disorders:**

Not known: pain in rectum and anal region

**Skin and subcutaneous tissue disorders:**

Not known: dermatitis allergic, hives, blisters, rash, itch

**General disorders and administration site disorders:**

Not known: redness, irritation, burning sensation, dryness

**Serious effects: tell your doctor straight away**

Steroids can cause serious mental health problems. These are common in both adults and children. They can affect about 5 in every 100 people taking medicines that contain steroids.

- Feeling depressed, including thinking about suicide
- Feeling high (mania) or moods that go up and down
- Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory.
- Feeling seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act of having feelings of being alone.

If you notice any of these problems **talk to a doctor straight away**.

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**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance,

Earlsfort Terrace, IRL – Dublin 2;

Tel: +353 1 6764971 ; Fax: +353 1 6762517.

Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE PROCTOFOAM**

Keep out of the sight and reach of children.

Do not use Proctofoam after the expiry date (EXP) which is stated on the canister and carton. The expiry date refers to the last day of that month.

- Do not expose to temperatures above 50°C as this is a pressurised container containing flammable propellant. Protect from sunlight.
- Do not store above 25°C.
- Do not refrigerate
- Keep away from sources of ignition
- Do not spray on a naked flame of anything hot
- Do not pierce or burn the container even after use.

Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Proctofoam contains:**

The active ingredients in Proctofoam are hydrocortisone acetate (1% w/w) and pramocaine hydrochloride (1% w/w).

The other ingredients are cetyl alcohol, emulsifying wax (containing cetostearyl alcohol and sortiban ester), methyl parahydroxybenzoate (E218), polyoxyethylene (10); stearyl ether, propylene glycol, propyl parahydroxybenzoate (E216), trolamine, purified water and propellant HP-70 consisting of isobutene and propane.

### **What Proctofoam looks like**

Proctofoam is a white rectal foam contained in a pressurised canister.

### **Contents of the pack**

Each pack contains canister and a plastic applicator. Each canister contains approximately 40 doses.

### **Product Authorisation holder in Ireland:**

Meda Health Sales Ireland Limited, Unit 34/35,  
Block A, Dunboyne Business Park, Dunboyne,  
Co Meath, Ireland.

### **Manufacturer**

Pharmasol Limited, North Way, Walworth Industrial Estate.  
Andover, SP10 5AZ, UK.

**This leaflet was last revised in September 2017**

**If this leaflet is difficult to see or read or you would like it in a different format, please contact:**

**Meda Health Sales**

**Ireland Limited, Unit 34/35,**

**Block A, Dunboyne Business Park,**

**Dunboyne, Co Meath, Ireland**