

Patient Information Leaflet

Proctofoam HC Rectal Foam

(Hydrocortisone acetate 1% w/w
& Pramocaine hydrochloride 1% w/w)

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 has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- Throughout this leaflet Proctofoam HC Rectal Foam is called Proctofoam.

Important:

- **Proctofoam is a steroid medicine**, prescribed for many different conditions, including serious illnesses
- **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 below). 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.**

Now read the rest of this leaflet.

It includes other important information on the safe and effective use of this medicine that might be especially important for you.

In this leaflet:

1. What Proctofoam is for
2. Before you use Proctofoam
3. How to use Proctofoam
4. Possible side effects
5. How to store Proctofoam
6. Further information

1. What Proctofoam is 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 corticosteroid (such as Proctofoam) is an effective way to treat various illnesses involving inflammation in the body.

Proctofoam reduces this 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. 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

Proctofoam is not for use in children

If any of the above applies to you talk to your doctor or pharmacist.

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).

If any of these applies to you, talk to your doctor before using Proctofoam.

Taking other medicines

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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.

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).

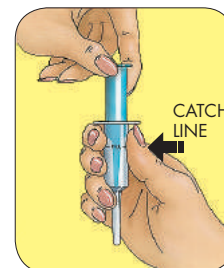
- The usual dose into the rectum is one applicator of foam two or three times per day and after each bowel evacuation up to a maximum of 4 times daily
- For the anal area expel a small amount of foam onto two fingers and apply to the affected area.

For rectal use only. Do not swallow

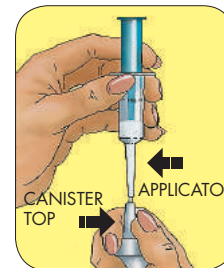
1. Shake the canister vigorously for 30 seconds before each use.



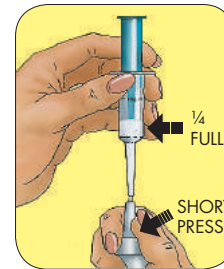
2. Withdraw the plunger until it stops at the catch line.



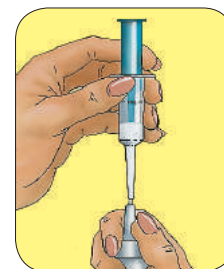
3. Hold the applicator upright and insert the canister top into the applicator tip. Make sure you hold the plunger and applicator body FIRMLY with your fingers.



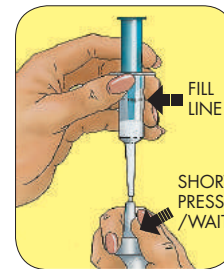
4. Press down gently on the canister top with your fingers, so that the foam fills about 1/4 of the applicator body. Only a short press is needed to do this.



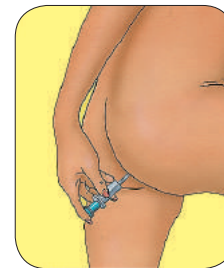
5. Wait for a few seconds until the foam stops expanding. **DO NOT** fill the applicator in one go. Always release the canister top after a short press.



6. Repeat steps 4 & 5 above until the foam expands to just reach the 'Fill' line. This normally takes 2 to 4 short press/wait.



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





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 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.

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 or having feelings of being alone.

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

Other side effects

If you get any of the following, keep using the medicine but tell your doctor:

- Unexpected fattening of the face, neck and body
- Irregular periods
- Hair starts to grow on your body (women)
- Dusky complexion with purple patches
- Skin thinning
- Allergic skin reaction
- Infection
- Burning sensation
- Itching.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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 reach and sight of children.

Do not use Proctofoam after the expiry date 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.
- Store in the original packaging to protect from sunlight.
- Store below 25°C. Do not refrigerate.
- Keep away from sources of ignition - No smoking.
- Do not spray on a naked flame or 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. Further information

What Proctofoam contains:

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

The other ingredients are cetyl alcohol, emulsifying wax (cetyl alcohol, sorbitan solution), methyl parahydroxybenzoate (E218), polyoxyethylene (10); stearyl ether, propylene glycol, propyl parahydroxybenzoate (E216), trolamine, purified water and propellant HP-70 consisting of isobutane 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.

Marketing Authorisation Holder in the UK:

Meda Pharmaceuticals Ltd, Skyway House, Parsonage Road, Takeley, Bishop's Stortford, CM22 6PU, UK.

Manufacturer

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

This leaflet was last approved in November 2013.

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

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MEDA

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