SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Proctofoam HC Rectal Foam

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone acetate 1.0% w/w and Pramocaine hydrochloride 1.0% w/w
1 g rectal foam contains 10 mg hydrocortisone acetate and 10 mg pramocaine hydrochloride.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Rectal foam
White

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the short term (not more than 5 – 7 days) relief of the symptoms of itching, irritation, discomfort or pain associated with local, non infective anal or perianal conditions.

4.2 Posology and method of administration

Posology
One applicator full per rectum two or three times daily and after each bowel evacuation (up to a maximum of four times daily). For perianal administration, apply a small quantity on two fingers.

Paediatric population
Not recommended for use in children.

Method of administration

See section 6.6 for handling instructions.

4.3 Contraindications

The medicinal product is contraindicated in patients with:

- Hypersensitivity to pramocaine hydrochloride, hydrocortisone acetate or to any of the excipients listed in section 6.1
- Bacterial, viral or fungal infections.

4.4 Special warnings and precautions for use

Not for prolonged use. Contact sensitization to local anaesthetics is common following prolonged application.

Seek medical advice if symptoms worsen, or do not improve within 7 days or if bleeding occurs.

Shake vigorously before use, use at room temperature, keep out of the reach of children. For external use only.

Rectal examination must be performed to exclude serious pathology before initiating treatment with Proctofoam.

Treatment should be administered with caution in patients with severe ulcerative disease because of their predisposition to perforation of the bowel wall.

Corticosteroids can cause elevation of blood pressure, salt and water retention in the blood, and increased urinary excretion of potassium. Therefore, patients with severe cardiac and/or renal insufficiency as well as patients with hypertension, will require careful monitoring.

Patients/and or carers should be warned that potentially severe psychiatric adverse reactions may occur with systemic steroids (see section 4.8). Symptoms typically emerge within a few days or weeks of starting the treatment. Risks may be higher with high doses/systemic exposure (see also section 4.5 pharmacokinetic interactions that can increase the risk of side effects), 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 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 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.

Live vaccines should not be given to individuals with impaired immune responsiveness. The antibody response to other vaccines may be diminished while on hydrocortisone therapy.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Methylhydroxybenzoate (E218) and propylhydroxybenzoate (E216) may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

No interactions have been reported with Proctofoam so far.

The active substance hydrocortisone is absorbed up to 5% in the gastrointestinal tract. For systemic hydrocortisone, interactions with the following medicinal products are known:

- Cardiac glycosides (potentiation of the effect of glycoside caused by potassium depletion),
- Potassium depleting agents, e.g. saluretic agents, amphotericin B (risk of hypokalemia),
- Coumarin derivatives (reduction of the anti-coagulation effect),
- Salicylates and other NSAIDs (increase in the risk of gastrointestinal bleeding),
- Antiretroviral agents (risk of adrenal supression),
- Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

4.6 Fertility, pregnancy and lactation

<u>Pregnancy</u>

Safety for use in pregnancy has not been established. There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities to foetal development including cleft palate and intrauterine growth retardation. There may be a very small risk of such effects in the human foetus.

The medicinal product should only be used in pregnancy if absolutely necessary. The benefit of treatment for the mother must be carefully weighed against the potential risks to the unborn child. Hydrocortisone should not be used extensively in pregnancy, that is in large amounts or for prolonged periods.

Breast-feeding
Safety for use in lactation has not been established. No data is available on the use of topical corticosteroids and local anaesthetic agents in nursing mothers. However, the product has been used by nursing mothers for many years without apparent ill consequence.
Hydrocortisone is excreted in breast milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Proctofoam therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

4.7 Effects on ability to drive and use machines

This medicinal product has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Within the system organ classes, adverse reactions are listed under headings of frequency (number of patients expected to experience the reaction), using the following categories:

Very common	(≥1/10)
Common	(≥1/100 to <1/10)
Uncommon	(≥1/1,000 to <1/100)
Rare	(≥1/10,000 to <1/1,000)
Very rare	(<1/10,000)
Not known	(cannot be estimated from the available data)

The following undesirable effects were observed with Proctofoam:

Immune system disorders
Not known: Hypersensitivity reactions including anaphylactic reaction, angiooedema

Eye disorders
Not known: Vision, blurred (see also section 4.4)

Gastrointestinal disorders:
Not known: Proctalgia, Anorectal discomfort

Skin and subcutaneous tissue disorders

Not known: Dermatitis allergic, urticaria, skin reactions (local, generalised) like blister, pruritus, rash

General disorders and administration site conditions
Not known: Application site reactions like erythema, irritation, burning sensation, dryness

Drugs of this class may cause systemic side effects (such as Cushing's syndrome, increased infection susceptibility), especially in long-term use, and if the medicine is not used as directed. The risk of systemic side effects when used at the correct dose by the local administration route is much lower than under systemic application.

A side effect that may occur is blurred vision (frequency not known) (see also section 4.4).

Although uncommon at this dosage; secondary infection and skin atrophy may occur. Systemic absorption of topical corticosteroids has produced reversible suppression of the hypothalamic - pituitary – adrenal axis.

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), behavioural 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

4.9 Overdose

Due to the rectal route of administration, the risk of overdose is small. Excess use of topical corticosteroids may produce systemic adverse effects.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:
Intestinal antiinflammatory agents, Corticosteroids acting locally.
ATC code: A07EA02
Agents for treatment of hemorrhoids and anal fissures for topical use. Local anaesthetics.
ATC code: C05AD07

Mechanism of action
The use of topically applied steroids in the treatment of inflammatory conditions is well known. Hydrocortisone acetate has anti-inflammatory activity resulting, at least in part, from binding with a steroid receptor.

Hydrocortisone has a membrane sealing effect, and inhibits of accumulation of neutrophiles and macrophages in the region of inflammation. Furthermore it reduces the migration of leukocytes and mastocytes into the tissue, inhibits the activity of lymphatic tissue and the secondary reaction of connective tissue (anti-proliferative, anti-oedematous effect).

Pramocaine hydrochloride is a surface anaesthetic and thus relieves the pain of anal and perianal conditions.

The use of steroids in inflammatory conditions is well known.

5.2 Pharmacokinetic properties

Bioavailability

The medicinal product acts mainly locally. After rectal administration, bioavailability of hydrocortisone acetate ranges between 2% and 3% in healthy subjects, and between 4% and 5% in patients.

5.3 Preclinical safety data

Animal studies have demonstrated a possible association between topical corticosteroids and foetal abnormalities, including cleft palate and intra-uterine growth retardation. The relevance of this finding to human beings has not been established.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetyl alcohol, Emulsifying wax, Methyl parahydroxybenzoate, Polyoxyethylene (10), Stearyl ether, Propylene glycol, Propyl

parahydroxybenzoate triethanolamine, Purified water, Propellant HP-70 consisting of:
-Isobutane
-Propane

6.2 Incompatibilities

Compatibility with barrier methods of contraception has not been demonstrated.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

Pressurised container containing flammable propellant. Protect from sunlight. Do not expose to temperatures above 50^{o}C. Do not spray on a naked flame or any incandescent material. Keep away from sources of ignition - no smoking. Do not pierce or burn, even after use.

Do not refrigerate. Store below 25^{o}C.

6.5 Nature and contents of container

Aerosol canister containing 20 g of product plus 1.2 g of inert propellant. A 10% overage of product and propellant is included to ensure the required number of doses can be achieved.

6.6 Special precautions for disposal

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

<u>For internal use</u>

2. Withdraw the plunger slowly until it stops at the catch line.
3. Holding UPRIGHT, insert the canister top into the applicator tip. Make sure you hold the plunger and applicator body FIRMLY with your fingers.
4. Fill applicator so that the foam fills about ¼ of the applicator body. Only a short press is needed to do this.
5. Wait until foam has stopped expanding.
6. Repeat steps 4 & 5 until the foam expands to just reach the “Fill” line. This normally takes 2 - 4 short press/waits.

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

For external use

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

These instructions are provided on the leaflet with illustrations to assist understanding.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Viatris Products Limited,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 46302/0114

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/06/2007

10 DATE OF REVISION OF THE TEXT

29/09/2025