

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Proctofoam H.C. 1.0% w/w & 1.0% w/w Rectal Foam

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone Acetate 1.0 % w/w

Pramocaine Hydrochloride 1.0 % w/w

Excipients: contains cetyl alcohol 0.300% w/w, methyl parahydroxybenzoate (E216) 0.050% w/w, propyl parahydroxybenzoate (E218) 0.005%w/w and propylene glycol 7.000% w/w. Also contains cetostearyl alcohol as a constituent of emulsifying wax.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Rectal foam.

White, aerosol foam.

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. In the management of anorectal inflammation fissures, pain and oedema associated with haemorrhoids or occurring post-operatively pruritis ani.

4.2 Posology and method of administration

One applicator full per rectum (3to 5mg hydrocortisone acetate) two or three times dailyand after each bowel evacuation (upto 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

Shake the canister vigorously for 30 seconds before each use. Use at room temperature. For rectal use only.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- Use in the presence of infections of viral, treponemal, fungal, tuberculosis and other bacterial infections.
- Use in the presence of ulcerations, fistulae or perforations.

4.4 Special warnings and precautions for use

Not for prolonged use. Contact sensitisation 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.

For external use only.

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

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 will require careful monitoring, and in patients with hypertension, regular blood pressure control is necessary.

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.

Some systemic absorption of corticosteroid will occur and this possibility should be borne in mind in relation to general disorders in electrolyte, mineral glucose and nitrogen equilibrium, and to the general inflammatory and immune responses.

Patients should not be vaccinated with live vaccines while on corticosteroid therapy.

Glucocorticoids can lead to positive results in doping tests.

Visual disturbance

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.

Proctofoam contains cetyl alcohol and cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis). Proctofoam also contains methyl parahydroxybenzoate (E216) and propyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm. This product also contains propylene glycol which may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interactions

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 suppression),

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

Safety for use in pregnancy and lactation has not been established.

Pregnancy

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. 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.

Breast-feeding

Hydrocortisone is excreted in breast milk. Safety for use in lactation has not been established.

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 ($\geq 1/10$)

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)

The following undesirable effects were observed with Proctofoam:

Immune system disorders

Not known: Hypersensitivity reactions including anaphylactic reaction, angioedema

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, 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.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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 neutrophils 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 (containing cetostearyl alcohol and sorbitan ester)
Methyl parahydroxybenzoate (E218)
Polyoxyethylene (10), stearyl ether
Propylene glycol
Propyl parahydroxybenzoate (E216)
Trolamine
Purified water
Propellant HP-70 consisting of:
Isobutane
Propane

6.2 Incompatibilities

Compatibility with barrier methods of contraception have not been demonstrated.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate.

Pressurised container containing flammable propellant. Protect from sunlight. Do not expose to temperatures above 50°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.

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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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

2. For internal use

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. Press down gently on the canister top with your fingers, so that the foam fills about $\frac{1}{4}$ 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. Repeats steps 4 & 5 above until the foam expands to just reach the 'Fill' line.
This normally takes 2 to 4 shot 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.

8. For external use

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.

7 MARKETING AUTHORISATION HOLDER

Mylan IRE Healthcare Limited
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Baldoyle Industrial Estate
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Ireland

8 MARKETING AUTHORISATION NUMBER

PA2010/035/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1978
Date of last renewal: 1st April 2008

10 DATE OF REVISION OF THE TEXT

July 2018