SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Colifoam 10% w/w Rectal Foam

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

White odourless rectal foam.

Hydrocortisone Acetate 10% w/w.

1 g rectal foam contains 100 mg hydrocortisone acetate.

Excipients with known effect:
Propylene Glycol, Stearyl Ether, Cetyl Alcohol, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate.

For a full list of excipients see Section 6.1

3 PHARMACEUTICAL FORM

Aerosol foam.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Ulcerative colitis, proctosigmoiditis and granular proctitis.

4.2 Posology and method of administration

Posology:

One applicatorful inserted into the rectum once or twice daily for two to three weeks and every second day thereafter.

Paediatric population
Safety and efficacy have not been established in the paediatric population.

Method of administration:

Shake the canister vigorously before filling the applicator. Withdraw the plunger and hold the container upright when filling the applicator. Fill the applicator just to the fill line. Insert the contents into the rectum following the instructions and explanatory pictures on the leaflet.

4.3 Contraindications

The medicinal product is contraindicated in patients with:

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Obstruction
- Abscess
- Perforation
- Peritonitis
- Fresh intestinal anastomoses
- Extensive fistulae
- Fungal, viral, tuberculous and other bacterial infections

4.4 Special warnings and precautions for use

General precautions common to all corticosteroid therapy should be observed during treatment with Colifoam, especially in the case of young children, due to the risk of growth retardation.

Treatment should be administered with caution in patients with severe ulcerative disease because of their predisposition to perforation of the bowel wall. Although uncommon at this dosage local irritation may occur.

When treating diabetic patients, it should be taken into consideration that they may need more insulin or oral anti-diabetics.

Special care should be taken when treating patients with myasthenia gravis.

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.

The medicinal product should not be used in patients with narrow- or wide-angle glaucoma.

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.

Patients under prolonged treatment should be observed for systemic effects.

Treatment should be discontinued gradually. Abrupt cessation of therapy should be avoided.

Cetyl alcohol may cause local skin reactions (e.g. contact dermatitis).

Propylene glycol may cause skin irritation.

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.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions have been reported with Colifoam 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),
- Macrolide antibiotics and ketoconazole (decrease in corticosteroid clearance),

- Anti-diabetic agents (reduction of the blood-sugar lowering effect),
- Coumarin derivatives (reduction of the anti-coagulation effect),
- Salicylates and other NSAIDs (increase in the risk of gastrointestinal bleeding),
- Antiretriviral 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.
- Substances which are mainly metabolized by CYP3A4, CYP3A5, CYP3A7.

4.6 Fertility, Pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of hydrocortisone in pregnant women.

Systemic and topical administration of corticosteroids to pregnant animals has shown reproductive toxicity (see section 5.3), and can cause abnormalities of foetal development.

The relevance of this finding to human beings has not been established but at present steroids should not be used extensively in pregnancy. The medicinal product should only be used in pregnancy if absolute necessary. The benefit of treatment for the mother must be carefully weighed against the potential risks for the foetus. Hydrocortisone should not be used extensively in pregnancy, that is in large amounts or for prolonged periods.

Breast-feeding

Hydrocortisone is excreted in breast milk. The medicinal product should not be used during breast-feeding. Otherwise, breast-feeding should be discontinued.

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 Colifoam:

Infections and infestations

Not known: Decreased resistance to infections

Immune system disorders

Not known: Hypersensitivity reactions including anaphylactic reaction, angioedema

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, dryness

Drugs of this class may cause systemic side effects (such as Cushing-Syndrome, decreased resistance to infections), 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 rare side effect that may occur is blurred vision (frequency not known) (see also section 4.4).

Although uncommon at this dosage, irritation may occur.

Side effects are very unusual with Colifoam, but long term frequent use may cause problems in some people. This is particularly so if the medicine is not used as directed. Although uncommon at this dosage, the following side effects may occur; unexpected fattening of the face, neck and body, periods may stop unexpectedly and hair starts to grow on the face (in women), dusky complexion with purple markings, local irritation.

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.

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

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Due to the rectal route of administration, the risk of overdose is small. Excessive use of Colifoam could lead to exacerbation of undesirable effects.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Intestinal anti-inflammatory agents, Corticosteroids acting locally
ATC code: A07EA02

Mechanism of action
The use of topically applied steroids in the treatment of ulcerative colitis, proctosigmoiditis and granular proctitis is well known. Hydrocortisone acetate has anti-inflammatory activity resulting, at least in part, from binding with a steroid receptor.
It 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).

5.2 Pharmacokinetic properties

Bioavailability

The topically applied steroid 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

Propylene Glycol Emulsifying Wax Polyoxyethylene (10) Stearyl Ether Cetyl Alcohol Methyl Hydroxybenzoate Propyl Hydroxybenzoate Triethanolamine Water Purified Propellant HP-70

6.2 Incompatibilities

None known.

6.3 Shelf life

60 months

6.4 Special precautions for storage

Pressurised container containing flammable propellant. Protect from sunlight and do not expose to temperatures about 50ºC. Store below 25ºC. Do not refrigerate. Do not spray on 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 20.8g of foam, plus a plastic applicator.

6.6 Special precautions for disposal

SEE LEAFLET.

1 Shake the canister vigorously before each use.

2 Fill applicator so that the foam fills about ¼ of the applicator body. Only a short press is needed to do this.

3 Wait until foam has stopped expanding.

4 Repeat step 2 until the foam expands to just reach the “Fill” line. This normally takes 2 4 short press/waits.

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

7. MARKETING AUTHORISATION HOLDER

Viatris Products Limited
20 Station Close
Potters Bar
Hertfordshire
EN6 1TL
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 46302/0122

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/11/2003

10 DATE OF REVISION OF THE TEXT

06/11/2025