SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

INN Name: Mometasone Furoate Cream

Trade mark name: FUMECON Cream

2. Qualitative and quantitative composition

Mometasone Furoate 0.1%

3. Pharmaceutical form

Cream

4. Clinical particulars

4.1 Therapeutic indications

Mometasone Furoate Cream is a medium potency corticosteroid indicated for the treatment of inflammatory and pruritic manifestations of psoriasis (excluding widespread plaque psoriasis) and atopic dermatitis in patients 2 years of age or older.

4.2 Posology and method of administration

Adults, including elderly patients and Children: A thin layer of Mometasone Furoate Cream should be applied to the affected areas of skin once daily.

Use of topical corticosteroids in children or on the face should be limited to the least amount compatible with an effective therapeutic regimen and duration of treatment should be no more than 5 days.

Mometasone Furoate Cream is not recommended for children under the age of 2.

4.3 Contraindication

FUMECON is contraindicated in facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, perianal and genital pruritis, napkin eruptions, bacterial (e.g. impetigo, pyodermas), viral (e.g. herpes simplex, herpes zoster and chickenpox verrucae vulgares, condylomata acuminata, molluscum contagiosum), parasitical and fungal (e.g. candida or dermatophyte) infections,

varicella, tuberculosis, syphilis or post-vaccine reactions. Mometasone Furoate Cream should not be used on wounds or on skin which is ulcerated. Mometasone Furoate Cream should not be used in patients who are sensitive to mometasone furoate or to other corticosteroids or to any of the ingredients in this medicine.

4.4 Special warnings and precautions for use

WARNINGS

Included as part of the **PRECAUTIONS** section.

PRECAUTIONS

Effects on Endocrine System

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of high-potency steroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure and young age.

Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression. This may be done by using the adrenocorticotropic hormone (ACTH) stimulation test.

In a study evaluating the effects of mometasone furoate cream on the HPA axis, 15 grams were applied twice daily for 7 days to six adult subjects with psoriasis or atopic dermatitis. The results show that the drug caused a slight lowering of adrenal corticosteroid secretion.

If HPA axis suppression is noted, an attempt should be made to gradually withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid. Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur, requiring supplemental systemic corticosteroids.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios [see **Use In Specific Populations**].

Allergic Contact Dermatitis

If irritation develops, FUMECON Cream should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than noting a clinical exacerbation as with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

Concomitant Skin Infections

If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used. If a favorable response does not occur promptly, use of FUMECON Cream should be discontinued until the infection has been adequately controlled.

4.5 Interaction with other medical products and other forms of interaction

No drug-drug interaction studies have been conducted with FUMECON Cream.

4.6 Pregnancy and lactation

Pregnancy

Teratogenic Effects - Pregnancy Category C

There are no adequate and well-controlled studies in pregnant women. Therefore, FUMECON Cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

When administered to pregnant rats, rabbits, and mice, mometasone furoate increased fetal malformations. The doses that produced malformations also decreased fetal growth, as measured by lower fetal weights and/or delayed ossification. Mometasone furoate also caused dystocia and related complications when administered to rats during the end of pregnancy.

In mice, mometasone furoate caused cleft palate at subcutaneous doses of 60 mcg/kg and above. Fetal survival was reduced at 180 mcg/kg. No toxicity was observed at 20 mcg/kg. (Doses of 20, 60, and 180 mcg/kg in the mouse are approximately 0.01, 0.02, and 0.05 times the estimated maximum clinical topical dose from FUMECON Cream on a mcg/m^2 basis.)

In rats, mometasone furoate produced umbilical hernias at topical doses of 600 mcg/kg and above. A dose of 300 mcg/kg produced delays in ossification, but no malformations. (Doses of

300 and 600 mcg/kg in the rat are approximately 0.2 and 0.4 times the estimated maximum clinical topical dose from FUMECON Cream on a mcg/m² basis.)

In rabbits, mometasone furoate caused multiple malformations (e.g., flexed front paws, gallbladder agenesis, umbilical hernia, hydrocephaly) at topical doses of 150 mcg/kg and above (approximately 0.2 times the estimated maximum clinical topical dose from FUMECON Cream on a mcg/m² basis). In an oral study, mometasone furoate increased resorptions and caused cleft palate and/or head malformations (hydrocephaly and domed head) at 700 mcg/kg. At 2800 mcg/kg most litters were aborted or resorbed. No toxicity was observed at 140 mcg/kg. (Doses at 140, 700, and 2800 mcg/kg in the rabbit are approximately 0.2, 0.9, and 3.6 times the estimated maximum clinical topical dose from FUMECON Cream on a mcg/m² basis.)

When rats received subcutaneous doses of mometasone furoate throughout pregnancy or during the later stages of pregnancy, 15 mcg/kg caused prolonged and difficult labor and reduced the number of live births, birth weight, and early pup survival. Similar effects were not observed at 7.5 mcg/kg. (Doses of 7.5 and 15 mcg/kg in the rat are approximately 0.005 and 0.01 times the estimated maximum clinical topical dose from FUMECON Cream on a mcg/m² basis.)

Nursing Mothers

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when FUMECON Cream is administered to a nursing woman.

Pediatric Use

FUMECON Cream may be used with caution in pediatric patients 2 years of age or older, although the safety and efficacy of drug use for longer than 3 weeks have not been established. Since safety and efficacy of FUMECON Cream have not been established in pediatric patients below 2 years of age, its use in this age group is not recommended.

In a pediatric trial, 24 atopic dermatitis subjects, of whom 19 subjects were age 2 to 12 years, were treated with FUMECON Cream once daily. The majority of subjects cleared within 3 weeks. FUMECON Cream caused HPA axis suppression in approximately 16% of pediatric subjects ages 6 to 23 months, who showed normal adrenal function by Cortrosyn test before starting treatment, and were treated for approximately 3 weeks over a mean body surface area of 41% (range 15%-94%). The criteria for suppression were: basal cortisol level of ≤ 5 mcg/dL, 30-minute post-stimulation level of ≤ 18 mcg/dL, or an increase of < 7 mcg/dL. Follow-up testing 2 to 4 weeks after trial completion, available for 5 of the subjects, demonstrated

suppressed HPA axis function in 1 subject, using these same criteria. Long-term use of topical corticosteroids has not been studied in this population

4.7 Effects on ability to drive and use machines

Mometasone Furoate Cream has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In controlled clinical trials involving 319 subjects, the incidence of adverse reactions associated with the use of FUMECON Cream was 1.6%. Reported reactions included burning, pruritus, and skin atrophy. Reports of rosacea associated with the use of FUMECON Cream have also been received. In controlled clinical trials (n=74) involving pediatric subjects 2 to 12 years of age, the incidence of adverse experiences associated with the use of FUMECON Cream was approximately 7%. Reported reactions included stinging, pruritus, and furunculosis.

The following adverse reactions were reported to be possibly or probably related to treatment with FUMECON Cream during clinical trials in 4% of 182 pediatric subjects 6 months to 2 years of age: decreased glucocorticoid levels, 2; paresthesia, 2; folliculitis, 1; moniliasis, 1; bacterial infection, 1; skin depigmentation, 1. The following signs of skin atrophy were also observed among 97 subjects treated with FUMECON Cream in a clinical trial: shininess, 4; telangiectasia, 1; loss of elasticity, 4; loss of normal skin markings, 4; thinness, 1; and bruising, 1.

The following additional local adverse reactions have been reported with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are: irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, striae, and miliaria.

4.9 Overdose

Topically applied FUMECON Cream can be absorbed in sufficient amounts to produce systemic effects [see WARNINGS AND PRECAUTIONS].

5. Pharmacological properties

5.1 Pharmacodynamic properties

Studies performed with FUMECON Cream indicate that it is in the medium range of potency as compared with other topical corticosteroids.

In a study evaluating the effects of mometasone furoate cream on the HPA axis, 15 grams were applied twice daily for 7 days to six adult subjects with psoriasis or atopic dermatitis. The cream was applied without occlusion to at least 30% of the body surface. The results showed that the drug caused a slight lowering of adrenal corticosteroid secretion [see **WARNINGS AND PRECAUTIONS**].

Ninety-seven pediatric subjects ages 6 to 23 months with atopic dermatitis were enrolled in an open-label HPA axis safety study. FUMECON Cream was applied once daily for approximately 3 weeks over a mean body surface area of 41% (range 15%-94%). In approximately 16% of subjects who showed normal adrenal function by Cortrosyn test before starting treatment, adrenal suppression was observed at the end of treatment with FUMECON Cream. The criteria for suppression were: basal cortisol level of ≤ 5 mcg/dL, 30-minute post-stimulation level of ≤ 18 mcg/dL, or an increase of < 7 mcg/dL. Follow-up testing 2 to 4 weeks after stopping treatment, available for 5 of the subjects, demonstrated suppressed HPA axis function in one subject, using these same criteria [see **Use in Specific Populations**].

5.2 Pharmacokinetic properties

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and the integrity of the epidermal barrier. Studies in humans indicate that approximately 0.4% of the applied dose of FUMECON Cream enters the circulation after 8 hours of contact on normal skin without occlusion. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

5.3 Preclinical safety data

Nonclinical Toxicology

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of FUMECON Cream. Long-term carcinogenicity studies of mometasone furoate were conducted by the inhalation route in rats and mice. In a 2-year carcinogenicity study in Sprague Dawley rats, mometasone furoate demonstrated no statistically significant increase of tumors at

inhalation doses up to 67 mcg/kg (approximately 0.04 times the estimated maximum clinical topical dose from FUMECON Cream on a mcg/m² basis). In a 19-month carcinogenicity study in Swiss CD-1 mice, mometasone furoate demonstrated no statistically significant increase in the incidence of tumors at inhalation doses up to 160 mcg/kg (approximately 0.05 times the estimated maximum clinical topical dose from FUMECON Cream on a mcg/m² basis).

Mometasone furoate increased chromosomal aberrations in an *in vitro* Chinese hamster ovary cell assay, but did not increase chromosomal aberrations in an *in vitro* Chinese hamster lung cell assay. Mometasone furoate was not mutagenic in the Ames test or mouse lymphoma assay, and was not clastogenic in an in vivo mouse micronucleus assay, a rat bone marrow chromosomal aberration assay, or a mouse male germ-cell chromosomal aberration assay. Mometasone furoate also did not induce unscheduled DNA synthesis in vivo in rat hepatocytes.

In reproductive studies in rats, impairment of fertility was not produced in male or female rats by subcutaneous doses up to 15 mcg/kg (approximately 0.01 times the estimated maximum clinical topical dose from FUMECON Cream, on a mcg/m² basis).

The safety and efficacy of the FUMECON Cream for the treatment of corticosteroid-responsive dermatoses were evaluated in two randomized, double-blind, vehicle-controlled clinical trials, one in psoriasis and one in atopic dermatitis. A total 366 subjects (12-81 years of age), of whom 177 received FUMECON Cream and 181 subjects received vehicle cream, were evaluated in these trials. FUMECON Cream or the vehicle cream were applied once daily for 21 days.

The two trials showed FUMECON Cream is effective in the treatment of psoriasis and atopic dermatitis.

6. Pharmaceutical particulars

6.1 List of excipients

Hexylene glycol
Purified Water
Titanium Dioxide
Aluminum Starch Octenylsuccinate
White Beeswax
White Soft Paraffin
Hydrogenated Soybean Lecithin
Phosphoric acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C in dry place away from sunlight.

Protect from light. Keep out of reach of children.

6.5 Nature and contents of container

Collapsible aluminum tube having a screw threaded neck finish sealed with an aluminum membrane. Each tube is supplied with a white polyethylene screw cap which has a piercing tip to puncture open the aluminum membrane on the neck.

Pack size: 15g

6.6 Special precautions for disposal and other handing

No special requirements

7. Registrant

Applicant: GENEITH PHARMACEUTICALS LIMITED.

Adress: No. 12 Adewale Crescent,Off Ewenla Street, Behind Unity Secondary School, Near Charity Bus Stop,Oshodi-Apapa Expressway, Oshodi, Lagos, NIGERIA

E-mail: geneith@geneithpharm.com

Contact person : EMMANUEL ELOCHUKWU UMENWA

Tel: 08129008556

8. Manufacturer

Manufacturer name: FRONT PHARMACEUTICAL PLC

Physical address: No.369 Baocheng Road, Xuancheng Economic and Technical Development Zone, Anhui, China

Tel: 86-0563-2625199

Fax: 86-0563-2625199

E-mail: export@frontpharm.com

9. Date of revision of the text

May 2024

10. DOSIMETRY (IF APPLICABLE)

N/A

11. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

N/A