Summary of Product Characteristics

1. Name of the medicinal product

Trade name : NIOSOL-F CREAM

Generic name : Clobetasol and Fusidic Acid Cream

2. Qualitative and Quantitative composition

A. Qualitative

Composition Composition:

Clobetasol Propionate BP 0.05 % w/w

Fusidic Acid BP 2.0 % w/w In

a cream base q.s.

For external use only

Pharmaceutical form

Cream

White homogenous semi-solid mass filled in printed lami tubes.

3. Clinical Particulars

Highly active corticosteroid with topical anti-inflammatory activity

ATC No.:

D07AD01 Clobetasol

D06AX01 Fusidic Acid

1. Therapeutic indications

Short courses for the treatment of more resistant dermatoses such as psoriasis (exclud- ing widespread plaque psoriasis), recalcitrant eczemas, lichen planus, discoid lupus erythematosus, and other skin conditions which do not respond satisfactorily to less active steroids.

2. Posology and method of administration Posology

Adult and children

Apply sparingly to the affected area once or twice daily until improvement occurs. As with other highly active topical steroid preparations, therapy should be discontinued when control is achieved. In the more responsive conditions this may be within a few days. The application frequency should be gradually reduced.

Repeated short courses of NIOSOL-F CREAM may be used to control exacerbations. If continuous steroid treatment is necessary, a less potent preparation should be used. In very resistant lesions, especially where there is hyperkeratosis, the anti-inflammatory effect of NIOSOL-F CREAM can be enhanced, if necessary, by occlud- ing the treatment area with polythene film. Overnight occlusion only is usually ade- quate to bring about a satisfactory response. Thereafter improvement can usually be maintained by application without occlusion.

Rarely, occlusion is necessary. In cases where an occlusive dressing is applied, caution is needed in order to avoid the risk of local and systemic adverse events.

NIOSOL-F CREAM should only be used for no more than 5 days on the face and eye- lids.

Method of administration

For topical administration.

Application of cream in adults:

- Two fingertips of cream will cover both hands or one foot
- Three fingertips of cream will cover one arm
- Six fingertips of cream will cover one leg
- Fourteen fingertips of cream will cover the front and back of the body.
- If no improvement is seen within two to four weeks, reassessment of the diagnosis, or referral, may be necessary.

Application of cream in children 1 year and older:

- The smaller the child the less you will need to use.
- A child of 4 years needs about a third of the adult amount.
- A course of treatment for a child should not normally last more than 5 days - unless your doctor has told you to use it for longer. The doctor may want to see the child eve- ry week, whilst using the cream.

Children below 1 year

NIOSOL-F CREAM is contraindicated in children below 1 year.

Children are more susceptible to local and systemic adverse events caused by topical corticosteroids, and should generally be treated for a shorter duration and with less po- tent substances than adults. NIOSOL-F CREAM should be used with caution in chil- dren, to ensure that the smallest possible dose is applied within the therapeutic range.

3. Contraindications

Hypersensitivity to the active substance or any of the
excipients. Rosacea

- Acne vulgaris
- Perioral dermatitis
- Perianal and genital pruritus
- Primary cutaneous viral infections (e.g. herpes simplex, chickenpox)

•The use of NIOSOL-F CREAM skin preparations is not indicated in the treatment of primary infected skin lesions caused by infection with fungi (e.g. candidiasis, tinea) or bacteria (e.g. impetigo)

•Dermatoses in children under one year of age, including dermatitis and napkin eruptions.

4. Special warnings and precautions for use

- Long-term continuous therapy should be avoided where possible, particularly in infants and children, as adrenal suppression can occur even without occlusion. If NIOSOL-F CREAM is required for use in children, it is recommended that the treatment should be reviewed weekly. It should be noted that the infant's napkin may act as an occlusive dressing.
- If used in children or on the face, courses should be limited if possible to five days and occlusion should not be used.
- The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema.
- If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result. If NIOSOL-F CREAM does enter the eye, the affected eye should be bathed in copious amounts of water.

  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
- Topical steroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important.

- Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and systemic administration of antimicrobial agents. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and so the skin should be cleansed before a fresh dressing is applied.
- During application of corticosteroids on large areas, especially under (plastic) occlusion or in skin folds, increased absorption may occur, which could lead to adrenal function inhibition.
- There have been a few reports in the literature of the development of cataracts in patients who have been using corticosteroids for prolonged periods of time. Although it is not possible to rule out systemic corticosteroids as a known factor, prescribers should be aware of the possible role of corticosteroids in cataract development.
- Niosol-F 500 micrograms/g Cream contains cetostearyl alcohol which can cause local skin reactions (e.g. contact dermatitis), propylene glycol which may cause skin irritation and chlorocresol which may cause allergic reactions.
- This product contains Potassium Sorbate and may caused local skin reactions, (e.g. contact dermatitis).
- This product contains Sodium lauryl sulphate and may cause local skin reactions (such as stinging or burning sensation) or incresase skin reactions caused by other products when applied on the same area.

5. Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed

6. Fertility, pregnancy and lactation

Pregnancy

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of fetal development including cleft palate and intrauterine growth retardation. The relevance of this finding to humans has not been established, therefore, topical steroids should not be used ex- tensively in pregnancy, i.e. in large amounts or for prolonged periods.

Breast-feeding

The safe use of clobetasol propionate during lactation has not been established.
It is not known whether the topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk.
Administration of clobetasol propionate during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.
If used during lactation clobetasol propionate should not be applied to the breasts to avoid accidental ingestion by the infant.

Fertility

There are insufficient fertility data available to indicate whether clobetasol propionate has any effect on fertility.

7. Effects on ability to drive and use machines

There are insufficient fertility data available to indicate whether clobetasol propionate has any effect on fertility.

8. Undesirable effects

The following adverse reactions have been identified during post-approval use of clobetasol propionate. Because these reactions are reported voluntarily from a popula- tion of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The frequency of these adverse events has therefore been classified as “unknown”.

Immune system disorders

Hypersensitivity

Local hypersensitivity reactions such as erythema, rash, pruritus, urticaria and allergic contact dermatitis may occur at the site of application and may resemble symptoms of the condition under treatment.

If signs of hypersensitivity appear, application should be stopped immediately.

Endocrine disorders

Features of Cushing's syndrome

As with other topical corticosteroids, prolonged use of large amounts, or treatment of extensive areas can result in sufficient systemic absorption to produce the features of Cushing's syndrome. This effect is more likely to occur in infants and children, and if occlusive dressings are used. In infants, the nappy may act as an occlusive dressing.

Provided the weekly dosage is less than 50g in adults, any suppression of the HPA axis is likely to be transient with a rapid return to normal values once the short course of steroid therapy has ceased. The same applies to children given proportionate dosage.

Eye disorders

Vision, blurred

Vascular disorders

Dilatation of the superficial blood vessels

Prolonged and intensive treatment with highly-active corticosteroid preparations may cause dilatation of the superficial blood vessels, particularly when occlusive dressings are used, or when skin folds are involved.

Skin and subcutaneous tissue disorders

Local skin burning, local atrophy, striae, thinning, pigmentation changes, hypertrichosis, ex acerbation of underlying symptoms, pustular psoriasis.

Prolonged and intensive treatment with highly-active corticosteroid preparations may cause local atrophic changes, such as thinning and striae.

Treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease.

Clobetasol may induce steroid-rosacea and steroid-acne.

9. Overdose

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse, the features of hypercortisolism may appear and in this situation topical steroids should be reduced or discontinued gradually, under medical supervision.

4. Pharmacological properties

1. P h a r m a c o d y n a m i c

Properties Clobetasol

Clobetasol propionate is a highly active corticosteroid with topical anti-inflammatory activity. The major effect of clobetasol propionate on skin is a non-specific anti-inflammatory response, partially due to vasoconstriction and decrease in collagen syn- thesis.

Fusidic Acid

Fusidic acid is a potent antibacterial agent. Fusidic acid and its salts show fat and water solubility and strong surface activity and exhibit unusual ability to penetrate intact skin. Concentrations of 0.03 - 0.12 mcg fusidic acid per ml inhibit nearly all strains of Staphylococcus aureus. Topical application of fusidic acid is also effective against streptococci, corynebacteria, neisseria and certain clostridia.

2. Pharmacokinetic properties

Percutaneous penetration of clobetasol propionate varies among individuals and can be increased by the use of occlusive dressings, or when the skin is inflamed or diseased.

Mean peak plasma clobetasol propionate concentrations of 0.63 ng/ml occurred in one study eight hours after the second application (13 hours after an initial application) of 30 g clobetasol propionate 500 micrograms/g ointment to normal individuals with healthy skin. Following the application of a second dose of 30 g clobetasol propionate cream 500 micrograms/g mean peak plasma concentrations were slightly higher than the ointment and occurred 10 hours after application.

In a separate study, mean peak plasma concentrations of approximately 2.3 ng/ml and 4.6 ng/ml occurred respectively in patients with psoriasis and eczema three hours after a single application of 25 g clobetasol propionate 500 micrograms/g ointment.

Following percutaneous absorption of clobetasol propionate, the drug probably follows the metabolic pathway of systemically administered corticosteroids, i.e. metabolised primarily by the liver and then excreted by the kidneys. However, systemic metabolism of clobetasol has never been fully characterised or quantified.

Fusidic Acid

In vitro studies show that fusidic acid can penetrate intact human skin. The degree of penetration depends on factors such as the duration of exposure to fusidic acid and the condition of the skin. Fusidic acid is excreted mainly in the bile with little excreted in the urine.

3. **Preclinical safety data**

Parenteral administration of corticosteroids, including clobetasol propionate, to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. Animal studies have indicated that intrauterine exposure to corticosteroids may contribute to the development of cardiovascular and meta- bolic diseases in adult life, but there is a lack of evidence for the occurrence of such effects in humans.

1. **Pharmaceutical particulars**
2. **List of Excipients**

Lafonics(CM-1000)
Hard Paraffin Wax
Light Liquid Paraffin
m-Cresol
Potassium Sorbate
Sodium lauryl Sulphate
Propylene glycol
Purified water
Ginol-1618 (Cetostearyl Alcohol)
Phenoxyethanol

3. **Incompatibilities**

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

4. **Shelf Life**

24 months form the date of manufacturing

Cream should be used within 30 days after opening the tube

5. Special Precautions for Storage

Store at a temperature below 30 ^{0}C. Protect from light. Do not freeze.

6. Nature and Contents of container

Pack 15 g soft mass in printed lami tube, with mono carton & printed insert.

7. Special precautions for disposal and other handling

Carefully read the instructions before use. Consult your doctor for further information.

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

7.0 Marketing Authorization Holder

KLM LABORATORIES PVT. LTD.

8. 0 Marketing Authorization Number

TAN 22 HM 0278

9.0 Date of First Authorization/Renewal of Authorization

19th July, 2022

10.0 Date of Revision of the Text