SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE MEDICINAL PRODUCT

1.1 Name of the Medicinal Product

FUSIDERMCREAM (Mometasone Furoate & Fusidic Acid Cream)

1.2 Strength

Composition:
Mometasone Furoate BP …… 0.1 % w/w
Fusidic Acid BP …….. 2.0% w/w
Cream base …….. q.s.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr. No.	Item	Specifi-cation	Label claim	Overages	STD. Qty. (Kg)
1.	Mometasone Furoate	BP	0.10%w/w	2.0%	0.204
2.	Fusidic Acid	BP	2.00%w/w	1.0%	4.040
3.	Light liquid paraffin	BP	----	----	7.000
4.	Cetostearyl Alcohol	BP	----	----	20.000
5.	Cetomacrogol 1000	BP	----	----	4.000
6.	Butylated Hydroxy Toluene	BP	----	----	0.200
7.	White petroleum jelly	BP	----	----	40.000
8.	Methyl Paraben	BP	----	----	0.400
9.	Sodium Benzoate	BP	----	----	0.400
10.	Propylene Glycol	BP	----	----	21.200
11.	Propyl Paraben	BP	----	----	0.060
12.	Purified water	BP	----	----	q.s

3. PHARMACEUTICAL FORM

Cream (Topical)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

It is indicated for use in inflammatory dermatoses where bacterial infection is present or likely to occur.

4.2 Posology and method of administration

Apply a small quantity to the affected area twice daily until a satisfactory response is obtained. A single treatment course should not normally exceed 2 weeks.

4.3 Contraindications:

It is contraindicated in patients with a history of hypersensitivity to Mometasone, Fusidic acid or any other component of the formulation.

4.4 Special warnings and precautions for use

• Patients with a history of allergic-type responses to other topical or oral corticosteroids (enhanced risk of sensitivity)
• Infection at or near treatment sites (risk of worsening/spread)
• Patients with evidence of preexisting skin atrophy (exacerbation)
• Diabetes mellitus (potential hyperglycemic action of Mometasone if sufficient absorption)
• Patients with glaucoma or cataracts (potential worsening if sufficient absorption of Mometasone)
• Pregnancy or breast-feeding period (safety not clearly established)
• May cause hypothalamic-pituitary-adrenal axis suppression, Cushing's syndrome, hyperglycemia, or glycosuria, especially in patients with liver failure
• Avoid occlusive dressings or use over large surface areas
• Face, groin, and axillae are more susceptible to adverse topical effects
• Children are more susceptible to systemic absorption and toxicity
• Mometasone may increase the risk of serious or fatal infection in individuals exposed to viral illnesses such as chickenpox or measles

4.5 Interaction with other medicinal products and other forms of interaction

The combination of Mometasone and anthralin topical (used to treat psoriasis) should not be used since concomitant use may increase the symptoms of psoriasis. It is therefore advisable to discontinue topical steroids one week before starting anthralin.

4.6 Pregnancy and lactation

Pregnancy: The use of topical Cream in pregnancy requires that the potential benefits be weighed against the possible hazards to the foetus. For Fusidic acid, no clinical data on exposed pregnancies are available. Animal studies do not indicate a direct or indirect harmful effect with respect to pregnancies, embryonal/foetal development, parturition or postnatal development. The safety and efficacy of Cream has not been established in pregnant women. It is not recommended in pregnant women.

Lactation: There is no clinical data available regarding the excretion of either Mometasone or Fusidic acid in breast milk. No effects on the sucking child are anticipated since the systemic exposure of the breast-feeding woman to Fusidic acid and Mometasone is negligible

following topical application. Nevertheless, the use of cream is not recommended in breast-feeding mothers.

Pediatric: Since safety and efficacy has not been established in pediatric patients below 12 years of age, its use in this age group is not recommended.

4.7 Effects on ability to drive and use machines
Not Known

4.8 Undesirable effects
Local reactions at the application site, including burning, irritation, pruritus, and skin atrophy, may develop with fixed-topical Mometasone 0.1% / Fusidic acid 2% in dermatitis patients. Most of these effects have been mild or moderate in severity. Discontinuation of therapy has been required in some patients due to local effects. Undesirable effects observed for corticosteroids include: Skin atrophy, telanglectasia and skin striae, especially during prolonged application, folliculitis, hypertrichosis, perioral dermatitis and adrenocortical suppression.

4.9 Overdose
Topically applied cream may be absorbed in sufficient amounts to produce systemic effects. Symptoms: Excessive prolonged use of topical corticosteroids can suppress the pituitary-adrenal function resulting in secondary adrenal insufficiency. Appropriate symptomatic treatment is indicated in the event of overdosage. Acute hypercorticoid symptoms are virtually reversible. Treat electrolyte imbalance if necessary. In case of chronic toxicity, slow withdrawal or corticosteroids is advised.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties
Mometasone is a synthetic corticosteroid which is highly effective but may have a lower incidence of adverse effects than other corticosteroids. Corticosteroids have multiple mechanisms of action including anti-inflammatory activity, immunosuppressive properties, and antiproliferative actions. Anti-inflammatory effects result from decreased formation, release and activity of the mediators of inflammation (e.g. kinins, histamine, liposomal enzymes, prostaglandins, leukotrienes) which reduces the initial manifestations of the inflammatory process. Corticosteroids inhibit margination and subsequent cell migration to the area of injury, and also reverse the dilation and increased vessel permeability in the area, resulting in decreased access of cells to the sites of injury. This vasoconstrictive action decreases serum extravasation, swelling and discomfort. The immunosuppressive properties decrease the response to delayed and immediate hypersensitivity reactions (e.g., type III and type IV). This results from inhibition of the toxic effect from antigen and antibody complexes that precipitate in vessel walls creating cutaneous allergic vasculitis, and by inhibiting the

action of lymphokines, target cells, and macrophages which together produce allergic contact dermatitis reactions. Additionally, the access of sensitized T lymphocytes and macrophages to target cells may also be prevented by corticosteroids. The antiproliferative effects reduce hyperplastic tissue characteristic of psoriasis. Fusidic acid is a true antibiotic, derived from the fungus *Fusidium coccineum*. Fusidic acid works by interfering with bacterial protein synthesis, specifically by preventing the translocation of the elongation factor G (EF-G) from the ribosome. Fusidic acid is only effective on gram-positive bacteria such as *Staphylococcus* species, *streptococcus* and *Corynebacterium* species. Fusidic acid inhibits bacterial replication and does not kill the bacteria, and is therefore termed "bacteriostatic". When applied topically, the antibacterial activity of Fusidic acid is not diminished in the presence of corticosteroid.

5.2 Pharmacokinetic properties

Absorption: When used singly, the systemic absorption of Mometasone furoate (0.1% ointment) is less that 1%. Metabolism: Absorbed Mometasone is extensively metabolized in the liver after topical application. Excretion: Following percutaneous absorption, topical corticosteroids are excreted primarily by the kidneys and to a small extent in the bile. The elimination half-life of Mometasone is 5.8 hours. There are no data which define the pharmacokinetics of Cream, following topical administration in man. However, *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.

5.3 Preclinical safety data

Not Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Propyl Paraben, Cetomacrogol-1000, White Petroleum Jelly, Sodium Benzoate, Methyl Paraben, Butylated Hydroxy Toluene, Propylene Glycol, Cetostearyl Alcohol, Light Liquid Paraffin, Purified Water.

6.2 Incompatibilities

None known

6.3 Shelf life

24 Months

6.4 Special precaution for storage

Store at a temperature not exceeding 30°C

6.5 Nature and contents of container
10 gm Lami tube packed in carton

6.6 Special precautions for disposal
Not applicable

7. APPLICANT
Yash Pharma laboratories Pvt. Ltd.
Unit No.1001, 10th floor, Dosti pinnacle,
Plot No.E-7, Road No.22,
Wagle Industrial Estate,
Thane (West) Thane-400604. (India)

8. MANUFACTURER
Yash Pharma laboratories Pvt. Ltd.
Khasara No.19-M,Village:Raipur,
Pargana:Bhagwanpur, Tehsil-Roorkee,
Dist:-Haridwar,Uttarakhand.
Pincode- 247667, India.

9. DATE OF REVISION OF THE TEXT
Not Aplicable

1.17.2 Patient information leaflet (For All Products not subject to Medical Prescription)

FUSIDERMCREAM (Mometasone Furoate & Fusidic Acid Cream)

COMPOSITION:

Composition:
Mometasone Furoate BP …… 0.1 % w/w
Fusidic Acid BP …….. 2.0% w/w
Cream base …… q.s.

PHARMACOLOGICAL CLASSIFICATION

Mometasone Furoate is a medium-potency topical synthetic corticosteroid with anti-inflammatory action.
Fusidic acid is a bacteriostatic antibiotic that is often used topically in creams.

PHARMACOLOGICAL ACTION

Anti-inflammatory effect of Mometasone results from decreased formation, release and activity of the mediators of inflammation (e.g. kinins, histamine, liposomal enzymes, prostaglandins, leukotrienes) which reduces the initial manifestations of the inflammatory process.
Fusidic acid works by interfering with bacterial protein synthesis, specifically by preventing the translocation of the elongation factor G (EF-G) from the ribosome. Fusidic acid inhibits bacterial replication and does not kill the bacteria, and is therefore termed "bacteriostatic".
Pharmacokinetics Absorption: When used singly, the systemic absorption of Mometasone furoate (0.1% ointment) is less that 1%. Metabolism: Absorbed Mometasone is extensively metabolized in the liver after topical application. Excretion: Following percutaneous absorption, topical corticosteroids are excreted primarily by the kidneys and to a small extent in the bile. The elimination half-life of Mometasone is 5.8 hours.
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.

INDICATIONS

Mometasone Furoate & Fusidic acid cream is indicated for use in inflammatory dermatoses where bacterial infection is present or likely to occur.

CONTRA-INDICATIONS

Mometasone Furoate & Fusidic acid cream is contraindicated in patients with a history of hypersensitivity to Mometasone, Fusidic acid or any other component of the formulation.

PRECAUTION

• Patients with a history of allergic-type responses to other topical or oral corticosteroids (enhanced risk of sensitivity)

• Diabetes mellitus (potential hyperglycemic action of Mometasone if sufficient absorption)
• Patients with glaucoma or cataracts (potential worsening if sufficient absorption of Mometasone)
• Pregnancy or breast-feeding period (safety not clearly established)
• May cause hypothalamic-pituitary-adrenal axis suppression, Cushing's syndrome, hyperglycemia, or glycosuria, especially in patients with liver failure
• Mometasone may increase the risk of serious or fatal infection in individuals exposed to viral illnesses such as chickenpox or measles

PREGNANCY AND LACTATION
Pregnancy: The safety and efficacy of Mometasone Furoate & Fusidic acid cream has not been established in pregnant women. Therefore, it is not recommended in pregnant women.
Lactation: There is no clinical data available regarding the excretion of either Mometasone or Fusidic acid in breast milk. Therefore, the use of Mometasone Furoate & Fusidic acid cream is not recommended in breast-feeding mothers.

DRUG INTERACTIONS
The combination of Mometasone and anthralin topical (used to treat psoriasis) should not be used since concomitant use may increase the symptoms of psoriasis. It is therefore advisable to discontinue topical steroids one week before starting anthralin.

DOSAGE AND DIRECTIONS FOR USE
Apply a small quantity of Mometasone Furoate & Fusidic acid cream to the affected area twice daily until a satisfactory response is obtained. A single treatment course should not normally exceed 2 weeks.

SIDE-EFFECTS
Undesirable effects observed for corticosteroids include: Skin atrophy, telanglectasia and skin striae, especially during prolonged application, folliculitis, hypertrichosis, perioral dermatitis and adrenocortical suppression, burning, irritation, pruritus, and skin atrophy.

OVERDOSAGE
Excessive prolonged use of topical corticosteroids can suppress the pituitary-adrenal function resulting in secondary adrenal insufficiency. Appropriate symptomatic treatment is indicated in the event of overdosage. Acute hypercorticoid symptoms are virtually reversible. Treat electrolyte imbalance if necessary. In case of chronic toxicity, slow withdrawal or corticosteroids is advised.

PRESENTATION
10 gm Lami tube packed in carton.

STORAGE INSTRUCTIONS
Store at a temperature not exceeding 30°C
Keep the tube well closed.

KEEP OUT OF REACH OF CHILDREN.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder

DOLO PHARMA HEALTHCARE LTD.
PUMPING HYDRAULIC SYSTEM HOUSE,
P.O.BOX 102976-00101
NAIROBI.

Manufacturer

Yash Pharma laboratories Pvt. Ltd.
At: Khasara No.19-M,Village:Raipur,
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