For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

MOMOZ F

1. Generic Name

Mometasone Furoate with Fusidic Acid Ointment

2. Qualitative and quantitative Composition:

Mometasone Furoate I.P…….0.1% w/w

Fusidic Acid I.P……...2.0 % w/w

In an ointment base ……q.s.

The excipients used are Salicylic Acid, White Soft Paraffin, Light Liquid Paraffin, White Beeswax, Hard Paraffin and Propylene Glycol.

3. Dosage form and strength

Dosage form: Ointment

Strength: Mometasone Furoate 0.1% w/w and Fusidic Acid I.P 2.0 % w/w

4. Clinical particulars

4.1. Therapeutic indication

For the treatment of dermatoses where secondary bacterial and/or candidial infection is present.

4.2. Posology and method of administration

Posology

Directions for use: As directed by Physician.

Method of administration

For external use only.

4.3. Contraindications

Momoz F is contraindicated in facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, perianal and genital pruritus, 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.

Momoz F should not be used on wounds or on skin which is ulcerated.

Momoz F should not be used in patients who are hypersensitivity to the active substances or to any of the excipients.

4.4. Special warnings and precautions for use

Mometasone Furoate

If irritation or sensitisation develop with the use of Momoz F, treatment should be withdrawn, and appropriate therapy instituted.

Should an infection develop, use of an appropriate antifungal or antibacterial agent should be instituted. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection is adequately controlled.

Systemic absorption of topical corticosteroids can produce reversible hypothalamic pituitary adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glycosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients applying a topical steroid to a large surface area or areas under occlusion should be evaluated periodically for evidence of HPA axis suppression.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

Paediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios. As the safety and efficacy of Mometasone Furoate in paediatric patients below 2 years of age have not been established, its use in this age group is not recommended.

Local and systemic toxicity is common especially following long continued use on large areas of damaged skin, in flexures and with polythene occlusion. If used in childhood, or on the face, occlusion should not be used. If used on the face, courses should be limited to 5 days and occlusion should not be used. Long term continuous therapy should be avoided in all patients irrespective of age.

Topical steroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of centralised 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.

As with all potent topical glucocorticoids, avoid sudden discontinuation of treatment. When long term topical treatment with potent glucocorticoids is stopped, a rebound phenomenon can develop which takes the form of a dermatitis with intense redness, stinging and burning. This can be prevented by slow reduction of the treatment, for instance continue treatment on an intermittent basis before discontinuing treatment.

Glucocorticoids can change the appearance of some lesions and make it difficult to establish an adequate diagnosis and can also delay the healing.

Mometasone Furoate topical preparations are not for ophthalmic use, including the eyelids, because of the very rare risk of glaucoma simplex or subcapsular cataract.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) corticosteroid use. If a patient present 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 of visual disturbances 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.

Fusidic Acid

Bacterial resistance among Staphylococcus aureus has been reported to occur with the use of topical MOMOZ F. As with all antibiotics, extended or recurrent use may increase the risk of developing antibiotic resistance.

Extended or recurrent use may increase the risk of developing contact sensitisation.

When MOMOZ F ointment is used on the face; care should be taken to avoid the eyes as the excipients in the ointment may cause conjunctival irritation.

4.5. Drugs interactions

None stated.

4.6. Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy

During pregnancy treatment with Momoz F should be performed only on the physician's order. Then, however, the application on large body surface areas or over a prolonged period should be avoided. There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. There are no adequate and well controlled studies with Momoz F in pregnant women and therefore the risk of such effects to the human foetus is unknown. However as with all topically applied glucocorticoids, the possibility that foetal growth may be affected by glucocorticoid passage through the placental barrier should be considered. There may therefore be a very small risk of such effects in the human foetus. Like other topically applied glucocorticoids, Momoz F should be used in pregnant women only if the potential benefit justifies the potential risk to the mother or the foetus.

Lactation

It is not known whether topical administration of Momoz F could result in sufficient systemic absorption to produce detectable quantities in breast milk. Momoz F should be administered to nursing mothers only after careful consideration of the benefit/risk relationship. If treatment with higher doses or long term application is indicated, breastfeeding should be discontinued

4.7. Effects on ability to drive and use machines

MOMOZ F administered topically has no or negligible influence on the ability to drive or to use machines.

4.8. Undesirable effects

Mometasone Furoate

Table 1: Treatment-related adverse reactions reported with Mometasone by body system and frequency

Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100); rare (≥1/10,000, <1/1,000); very rare (<1/10 000,); not known (cannot be estimated from available data)

Infections and infestations	
Not known	Infection, furuncle
Very rare	Folliculitis
Nervous system disorders	
Not known	Paraesthesia
Very rare	Burning sensation
Skin and subcutaneous tissue disorders	

Not known	Dermatitis, contact,skin hypopigmentation, hypertrichosis, skin, striae, dermatitis acneiform, skin atrophy
Very rare	Pruritus
General disorders and administration site conditions	
Not known	Application site pain, application site reactions
Eye disorders	
Not Known	Vision blurred

Local adverse reactions reported infrequently with topical dermatologic corticosteroids include: skin dryness, irritation, dermatitis, perioral dermatitis, maceration of the skin, malaria and telangiectasia.

Local adverse reactions reported infrequently with topical dermatologic corticosteroids include: skin dryness, irritation, dermatitis, perioral dermatitis, maceration of the skin, miliaria and telangiectasiae.

Paediatric patients may demonstrate greater susceptibility to topical corticosteroid induced hypothalamic pituitary adrenal axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

Chronic corticosteroids therapy may interfere with the growth and development of children.

Fusidic Acid

The estimation of the frequency of undesirable effects is based on a pooled analysis of data from reported clinical trials and from spontaneous reporting.

The most frequently reported adverse reactions during treatment are various skin reactions such as pruritus and rash, followed by various application site conditions such as pain and irritation, which all occurred in less than 1% of patients.

Hypersensitivity and angioedema have been reported.

Immune system disorders	
Rare	Hypersensitivity
Eye disorders	
Rare	Conjunctivitis
Skin and subcutaneous tissue disorders	
Uncommon	Dermatitis (including dermatitis contact, eczema) Rash* Pruritus Erythema *Various types of rash reactions such as erythematous, pustular, vesicular, maculo-papular and papular have been reported. Rash generalised has also occurred.
Rare	Angioedema Urticaria Blister
General disorders and administration site conditions	

Uncommon	Application site pain (including skin burning sensation) Application site irritation

Paediatric population

Frequency, type, and severity of adverse reactions in children are expected to be the same as in adults.

Reporting of 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. Report suspected adverse reactions via any point of contact available at www.torrentpharma.com.

4.9. Overdose

Mometasone Furoate

Excessive, prolonged use of Momoz F can suppress hypothalamic-pituitary adrenal function resulting in secondary adrenal insufficiency which is usually reversible.

If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application or to substitute a less potent steroid.

The steroid content of each container is so low as to have little or no toxic effect in the unlikely event of accidental oral ingestion.

5. Pharmacological properties

5.1. Mechanism of Action

Mometasone Furoate

Mometasone Furoate exhibits marked anti-inflammatory activity and marked anti-psoriatic activity in standard animal predictive models.

Fusidic acid

Fusidic acid belongs to a unique group of antibiotics, the fustians, which act to inhibit bacterial protein synthesis by blocking the lengthening of factor G. This is to prevent it from associating with ribosomes and GTP, thus preventing energy supply to the synthesis process.

5.2. Pharmacodynamic properties

Mometasone Furoate

Mometasone furoate exhibits marked anti-inflammatory activity and marked anti-psoriatic activity in standard animal predictive models.

In the croton oil assay in mice, mometasone was equipotent to betamethasone valerate after single application and about 8 times as potent after five applications.

In guinea pigs, mometasone was approximately twice as potent as betamethasone valerate in reducing m. ovalis-induced epidermal acanthosis (i.e. anti-psoriatic activity) after 14 applications.

Fusidic acid

Fusidic acid is a potent topical 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 microgram/ml inhibit nearly all strains of Staphylococcus aureus.

Topical application of fusidic acid is also effective against streptococci, corynebacteria, neisseria and certain clostridia.

5.3. Pharmacokinetic properties

Mometasone Furoate

Pharmacokinetic studies have indicated that systemic absorption following topical application of Mometasone Furoate ointment 0.1% is minimal, approximately 0.4% of the applied dose in man, the majority of which is excreted within 72 hours following application. Characterisation of metabolites was not feasible owing to the small amounts present in plasma and excreta.

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.

6. Nonclinical properties

6.1. Animal Toxicology or Pharmacology

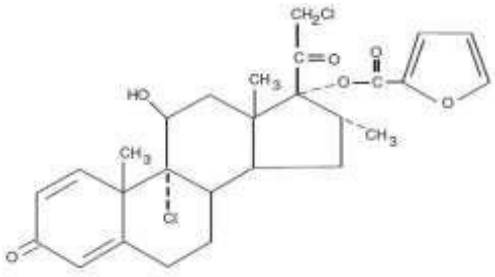
No preclinical data is available.

7. Description

Mometasone Furoate

Mometasone furoate is a synthetic corticosteroid with anti-inflammatory activity.

Chemically, Mometasone furoate is 9α,21-dichloro-11β-hydroxy-16α-methyl-3,20-dioxopregna-1,4-diene-3,20-dione 17-yl-furan-2-carboxylate, with the empirical formula $C_{27}H_{30}Cl_2O_6$, a molecular weight of 521.4 and the following structural formula:



Mometasone furoate is a white or almost white powder which is soluble in acetone and in dichloromethane; slightly soluble in ethanol (95%); practically insoluble in water.

Fusidic acid

Fusidic acid is ent-16α-acetyloxy-3β-dihydroxy-4β, 8β,14β-trimethyl-18-nor-5β, 10α chlolesta (17Z)-17(20), 24-dien-21-oic acid hemihydrate, with empirical formula $C_{31}H_{48}O_6$,1/2H_2O, a molecular weight of 525.7. It is a white, crystalline powder which is freely soluble in ethanol (95%) and in chloroform; sparingly soluble in ether'; practically insoluble in water.

Mometasone Furoate with Fusidic Acid Ointment is white Colour smooth ointment free from lumps. The excipients used are Salicylic Acid, White Soft Paraffin, Light Liquid Paraffin, White Beeswax, Hard Paraffin and Propylene Glycol.

8. Pharmaceutical particulars

8.1. Incompatibilities

Not applicable

8.2. Shelf-life

Do not use later than date of expiry.

8.3. Packaging information

MOMOZ F is available in 10g tube.

8.4. Storage and handing instructions

Store at a temperature not exceeding 25ºC. Do not freeze. Keep out of reach of children. Close the cap tightly after use.

9. Patient Counselling Information

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies
- Have kidney or liver problems
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illness
- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

10. Details of manufacturer

Manufactured by:

Helios Pharmaceuticals (Div of P.K.T.P. Pvt. Ltd.)

Village Malpur, P.O. Bhud, Tehsil Nalagarh, Baddi Dist. Solan (H.P.) – 173205

11. Details of permission or licence number with date

Mfg Lic No. MB/05/281 issued on 01.04.2016.

12. Date of revision

Feb-2026

MARKETED BY

TORRENT PHARMA

TORRENT PHARMACEUTICALS LTD.

IN/MOMOZ F 0.1% w/w, 2.0 % w/w/Feb-26/02/PI