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

FLUTIBACT SKIN OINTMENT

1. GENERIC NAME

Fluticasone Propionate and Mupirocin Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Micronised Fluticasone Propionate
Contains:

Fluticasone Propionate I.P.	0.005 % w/w
Mupirocin I.P.	2.0 % w/w

in a water soluble Ointment base

List of Excipients

Polyethylene Glycol 400, PEG 3350.

3. DOSAGE FORM AND STRENGTH

Ointment

For information on strength refer *2. Qualitative and Quantitative Composition* above.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

FLUTIBACT SKIN OINTMENT is indicated for the treatment and management of steroid-responsive inflammatory disorders of the skin where secondary bacterial infections are present, suspected or likely to occur.

These include the following:
Atopic dermatitis; nummular dermatitis (discoid eczemas); prurigo nodularis; psoriasis (excluding widespread plaque psoriasis); lichen simplex chronicus (neurodermatitis) and lichen planus; seborrhoeic dermatitis; irritant or allergic contact dermatitis; discoid lupus erythematosus; insect bite reactions; miliaria (prickly heat)**.**

4.2 Posology and Method of Administration

Adults, elderly, children and infants aged 3 months and over

Ointments are especially appropriate for dry, lichenified or scaly lesions.

Apply a thin film of *FLUTIBACT SKIN OINTMENT* to cover the affected areas twice daily for up to 10 days depending on the response.

If the condition worsens or does not improve within 10 days, treatment and diagnosis should be re-evaluated.

The treated area may be covered by a dressing.

Do not mix with other preparations as there is a risk of dilution, resulting in a reduction in the antibacterial activity and potential loss of stability of the mupirocin in the ointment.

Atopic dermatitis

Therapy with topical corticosteroids should be gradually discontinued once control is achieved and an emollient continued as maintenance therapy.

Rebound of pre-existing dermatoses can occur with abrupt discontinuation of topical steroids especially with potent preparations.

Children over 3 months

Children are more likely to develop local and systemic side effects of topical corticosteroids and, in general, require shorter courses and less potent agents than adults.

Care should be taken when using *FLUTIBACT SKIN OINTMENT* to ensure the amount applied is the minimum that provides therapeutic benefit.

Elderly

Clinical studies of fluticasone propionate have not identified differences in responses between the elderly and younger patients. The greater frequency of decreased hepatic or renal function in the elderly may delay elimination if systemic absorption occurs. Therefore, the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

Renal/Hepatic Impairment

In case of systemic absorption of fluticasone propionate (when application is over a large surface area for a prolonged period) metabolism and elimination may be delayed therefore increasing the risk of systemic toxicity. Therefore, the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

4.3 Contraindications

FLUTIBACT SKIN OINTMENT is contraindicated in:

- Patients with a history of hypersensitivity to any of the ingredients of the preparation

The following conditions should not be treated with *FLUTIBACT SKIN OINTMENT*:

- Rosacea
- Acne vulgaris
- Perioral dermatitis
- Pruritus without inflammation
- Perianal and genital pruritus
- Primary cutaneous viral, yeast, fungal and bacterial infections
- Secondarily infected skin lesions caused by virus, fungi and/or yeast
- Dermatoses in infants under 3 months of age, including dermatitis and nappy rash.

4.4 Special Warnings and Precautions for Use

In the rare event of possible sensitisation reaction or severe local irritation occurring with the use of *FLUTIBACT SKIN OINTMENT*, treatment should be discontinued, the product should be wiped off and appropriate alternative therapy instituted.

Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. Although this is less likely to occur with topically applied mupirocin, if prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately, and the patient investigated further.

As with other antibacterial products, prolonged use may result in overgrowth of non-susceptible organisms.

Polyethylene glycol can be absorbed from open wounds and damaged skin and is excreted by the kidneys. In common with other polyethylene glycol-based ointments, *FLUTIBACT SKIN OINTMENT* should not be used in conditions where absorption of large quantities of polyethylene glycol is possible, especially if there is evidence of moderate or severe renal impairment.

Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals as a result of increased systemic absorption of topical steroids. If either of the above is observed, withdraw the drug gradually by reducing the frequency of application. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency (see *4.8 Undesirable Effects*).

Risk factors for increased systemic effects are:

- Potency and formulation of topical steroid
- Duration of exposure
- Application to a large surface area
- Use on occluded areas of skin [e.g. on intertriginous areas or under occlusive dressings (in infants the nappy may act as an occlusive dressing)]

- Increasing hydration of the stratum corneum
- Use on thin skin areas such as the face
- Use on broken skin or other conditions where the skin barrier may be impaired
- In comparison with adults, children and infants may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic adverse effects. This is because children have an immature skin barrier and a greater surface area to body weight ratio compared with adults.

Visual disturbance has been reported by patients using systemic and /or topical corticosteroids. If a patient has blurred vision or other visual disturbances, consider evaluation of possible causes which may include cataract, glaucoma, and central serous chorioretinopathy.

Children

In infants and children under 12 years of age, long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression is more likely to occur.

Use in psoriasis

Topical steroids should be used with caution in psoriasis as 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 have been reported in some cases. If used in psoriasis, careful patient supervision is important.

Application to the face

Prolonged application to the face is undesirable as this area is more susceptible to atrophic changes.

Application to the eyelids

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye as cataract and glaucoma might result from repeated exposure.

Avoid contact with the eyes. If contaminated, the eyes should be thoroughly irrigated with water until the ointment residues have been removed.

Concomitant fungal/viral infection

Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have fungal/viral infection. Any spread of fungal/viral infection requires withdrawal of topical corticosteroid therapy and administration of appropriate antimicrobial therapy.

Infection risk with occlusion

Bacterial infection is encouraged by the warm, moist conditions within skin folds or caused by occlusive dressings. When using occlusive dressings, the skin should be cleansed before a fresh dressing is applied.

Chronic leg ulcers

Topical corticosteroids are sometimes used to treat the dermatitis around chronic leg ulcers. However, this use may be associated with a higher occurrence of local hypersensitivity reactions and an increased risk of local infection.

4.5 Drug Interactions

Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

4.6 Use in Special Populations

Fertility

There are no data in humans to evaluate the effect of topical corticosteroids on fertility *(*see *6 Nonclinical Properties).*

There are no data on the effects of mupirocin on human fertility. Studies in rats showed no effects on fertility (see *6 Nonclinical Properties*).

Pregnancy

There are limited data from the use of fluticasone propionate in pregnant women.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. (see *6 Nonclinical Properties*). The relevance of this finding to humans has not been established;

Adequate human data on use of mupirocin during pregnancy not available. Studies in animals do not indicate reproductive toxicity (see *6 Nonclinical Properties*).

However, administration of *FLUTIBACT SKIN OINTMENT* during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus. The minimum quantity should be used for the minimum duration.

Lactation

The safe use of topical corticosteroids 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.

When measurable plasma levels were obtained in lactating laboratory rats following subcutaneous administration there was evidence of fluticasone propionate in the milk.

Adequate human and animal data on use of mupirocin during lactation are not available.

Administration of *FLUTIBACT SKIN OINTMENT* during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

If used during lactation, *FLUTIBACT SKIN OINTMENT* should not be applied to the breasts to avoid accidental ingestion by the infant.

Children over 3 months

Children are more likely to develop local and systemic side effects of topical corticosteroids and, in general, require shorter courses and less potent agents than adults.

Care should be taken when using *FLUTIBACT SKIN OINTMENT* to ensure the amount applied is the minimum that provides therapeutic benefit.

Elderly

Clinical studies of fluticasone propionate have not identified differences in responses between the elderly and younger patients. The greater frequency of decreased hepatic or renal function in the elderly may delay elimination if systemic absorption occurs. Therefore, the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

Renal/Hepatic Impairment

In case of systemic absorption of fluticasone propionate (when application is over a large surface area for a prolonged period) metabolism and elimination may be delayed therefore increasing the risk of systemic toxicity. Therefore, the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit

4.7 Effects on Ability to Drive and Use Machines

There have been no studies to investigate the effect of *FLUTIBACT SKIN OINTMENT* on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical *FLUTIBACT SKIN OINTMENT.*

4.8 Undesirable Effects

In absence of availability of adverse event data on the fixed dose combination of fluticasone propionate and mupirocin, adverse event data of the individual ingredients is presented below.

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: 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) and very rare (<1/10,000), including isolated reports.

Fluticasone Propionate

Post-Marketing Data

Infections and infestations
Very rare: Opportunistic infection.

Immune system disorders
Very rare: Hypersensitivity.

Endocrine disorders
Very rare: Hypothalamic-pituitary adrenal (HPA) axis suppression:

- Increased weight/obesity
- Delayed weight gain/growth retardation in children
- Cushingoid features (e.g. moon face, central obesity)
- Decreased endogenous cortisol levels
- Hyperglycaemia/glucosuria
- Hypertension
- Osteoporosis
- Cataract
- Glaucoma

Skin and subcutaneous tissue disorders
Common: Pruritus.
Uncommon: Local skin burning.
Very rare: Skin thinning, atrophy, striae, telangiectasias, pigmentation changes, hypertrichosis, allergic contact dermatitis, exacerbation of underlying symptoms, pustular psoriasis, erythema, rash, urticaria.

Mupirocin

Common and uncommon adverse reactions were determined from pooled safety data from a clinical trial population of 1573 treated patients encompassing 12 clinical studies. Very rare adverse reactions were primarily determined from post-marketing experience data and therefore refer to reporting rate rather than true frequency.

Immune system disorders:

Very rare: Systemic allergic reactions including anaphylaxis generalised rash, urticaria and angioedema have been reported with mupirocin ointment.

Skin and subcutaneous tissue disorders

Common: Burning localised to the area of application.

Uncommon: Itching, erythema, stinging and dryness localised to the area of application. Cutaneous sensitisation reactions to mupirocin or the ointment base.

4.9 Overdose

Symptoms and Signs

Topically applied fluticasone propionate may be absorbed in sufficient amounts to produce systemic effects. Acute over dosage is very unlikely to occur, however, in the case of chronic over dosage or misuse the features of hypercortisolism may appear *(*see *4.8 Undesirable Effects).*

There is currently limited experience with overdosage of mupirocin ointment.

Treatment

In the event of overdose, *FLUTIBACT SKIN OINTMENT* should be withdrawn gradually by reducing the frequency of application because of the risk of glucocorticosteroid insufficiency.

There is no specific treatment for an overdose of mupirocin. In the event of overdose, the patient should be treated supportively with appropriate monitoring as necessary.

Further management should be as clinically indicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of Action

Fluticasone propionate

Topical corticosteroids have anti-inflammatory, antipruritic, and vasoconstrictive properties. They act as anti-inflammatory agents via multiple mechanisms to inhibit late phase allergic reactions including decreasing the density of mast cells, decreasing chemotaxis and activation of eosinophils, decreasing cytokine production by lymphocytes, monocytes, mast cells and eosinophils, and inhibiting the metabolism of arachidonic acid.

Fluticasone propionate is a glucocorticoid with high topical anti-inflammatory potency but low HPA-axis suppressive activity after dermal administration. It therefore has a therapeutic index which is greater than most of the commonly available steroids.

It shows high systemic glucocorticoid potency after subcutaneous administration but very weak oral activity, probably due to metabolic inactivation. *In vitro* studies show a strong affinity, for and agonist activity at, human glucocorticoid receptors.

Mupirocin

Mupirocin is a novel antibiotic produced through fermentation of *Pseudomonas fluorescens.* Mupirocin inhibits isoleucyl transfer-RNA synthetase, thereby arresting bacterial protein synthesis.

Due to this particular mode of action and its unique chemical structure, mupirocin does not show any cross-resistance with other clinically available antibiotics.

Mupirocin has bacteriostatic properties at minimum inhibitory concentrations and bactericidal properties at the higher concentrations reached when applied locally.

5.2 Pharmacodynamic Properties

Fluticasone propionate

Fluticasone propionate has no unexpected hormonal effects, and no overt, marked effects upon the central and peripheral nervous systems, the gastrointestinal system, or the cardiovascular or respiratory systems.

Mupirocin

Activity

Mupirocin is a topical antibacterial agent showing *in vivo* activity against *Staphylococcus aureus* (including methicillin-resistant strains), *S. epidermidis* and beta-haemolytic *Streptococcus* species.

The *in vitro* spectrum of activity includes the following bacteria:

Commonly Susceptible Species:
Staphylococcus aureus [1,2]
Staphylococcus epidermidis[1,2]
Coagulase-negative staphylococci[1,2]
Streptococcus species[1]
Haemophilus influenzae
Neisseria gonorrhoeae
Neisseria meningitidis
Moraxella catarrhalis
Pasteurella multocida

[1]Clinical efficacy has been demonstrated for susceptible isolates in approved clinical indications..
[2] Including beta-lactamase producing strains and methicillin-resistant strain

Resistant Species:
Corynebacterium species
Enterobacteriaceae
Gram negative non-fermenting rods
Micrococcus species
Anaerobes

Mupirocin susceptibility (MIC) breakpoints for *Staphylococcus spp.*

Susceptible: less than or equal to 1 microgram/ml

Intermediate: 2 to 256 micrograms/ml

Resistant: greater than 256 micrograms/ml

Resistance mechanisms

Low-level resistance in staphylococci (MICs 8 to 256 micrograms/ml) has been shown to be due to changes in the native isoleucyl tRNA synthetase enzyme. High-level resistance in staphylococci (MICs greater than or equal to 512 micrograms/ml) has been shown to be due to a distinct, plasmid encoded isoleucyl tRNA synthetase enzyme. Intrinsic resistance in Gram negative organisms such as the Enterobacteriaceae could be due to poor penetration into the bacterial cell.

5.3 Pharmacokinetic Properties

Absorption

Fluticasone propionate

Bioavailability is very low after topical or oral administration, due to limited absorption through the skin or from the gastrointestinal tract, and because of extensive first pass metabolism.

Oral bioavailability approaches zero, due to poor absorption and extensive first pass metabolism. Therefore, systemic exposure of fluticasone propionate from any ingestion of *FLUTIBACT SKIN OINTMENT* will be low.

Mupirocin

Mupirocin is poorly absorbed through intact human skin.

Distribution

Fluticasone propionate

Distribution studies have shown that only minute traces of orally administered compound reach the systemic circulation and that any systemically available fluticasone propionate is rapidly eliminated in the bile and excreted in the faeces.

Fluticasone propionate does not persist in any tissue and does not bind to melanin.

Metabolism

Fluticasone propionate

Pharmacokinetic data for the rat and dog indicates rapid elimination and extensive metabolic clearance of fluticasone propionate. In man too, metabolic clearance is extensive, and elimination is consequently rapid. Thus, drug entering the systemic circulation via the skin will be rapidly inactivated. The major route of metabolism is hydrolysis to a carboxylic acid, which has very weak glucocorticoid or anti-inflammatory activity.

Mupirocin

Mupirocin is suitable only for topical application. Following i.v. or oral administration, or if mupirocin is absorbed (e.g. through broken/diseased skin) mupirocin is rapidly metabolised to inactive monic acid.

Elimination

Fluticasone propionate

In all test animal species the route of excretion was independent of the route of administration of fluticasone propionate. Excretion is predominantly faecal and is essentially complete within 48 hours.

Mupirocin

Mupirocin is rapidly eliminated from the body by metabolism to its inactive metabolite monic acid which is rapidly excreted by the kidney.

Special Patient Populations

Elderly patients: No restrictions unless there is evidence of moderate or severe renal impairment (see *4.4 Special Warnings and Precautions for Use*).

6. NONCLINICAL PROPERTIES

6.1 Animal Toxicology and Pharmacology

Carcinogenesis

Fluticasone propionate

Long-term topical and oral studies in animals to investigate the carcinogenic potential of fluticasone propionate did not show any evidence of carcinogenicity.

Mupirocin

Carcinogenicity studies with mupirocin have not been conducted.

Genotoxicity

Fluticasone propionate

Fluticasone propionate was not shown to be mutagenic in a range of *in vitro* bacterial and mammalian cell assays.

Mupirocin

Mupirocin was not mutagenic in *Salmonella typhimurium* or *Escherichia coli* (Ames assay). In a Yahagi assay, small increases in *Salmonella typhimurium* TA98 were observed at highly cytotoxic concentrations. In an *in vitro* mammalian gene mutation assay (MLA), no increase in mutation frequency was observed in the absence of metabolic activation. In the presence of metabolic activation, small increases in mutation frequency were observed at highly cytotoxic concentrations. However, no effects were observed in, yeast cell assays for gene conversion/mutation, an *in vitro* human lymphocyte assay or in an *in vitro* unscheduled DNA synthesis (UDS) assay. Furthermore, an *in vivo* mouse micronucleus assay (chromosome damage) and a rat Comet assay (DNA strand breakage) were negative, indicating the small increases observed at highly cytotoxic concentrations *in vitro* do not translate to the *in vivo* situation.

Reproductive Toxicology

Fertility

Fluticasone propionate

In a fertility and general reproductive performance study in rats, fluticasone propionate administered subcutaneously to females at up to 50 micrograms/kg per day and to males up to 100 micrograms/kg per day (later reduced to 50 micrograms/kg per day) had no effect upon mating performance or fertility.

Mupirocin

Mupirocin administered subcutaneously to male rats 10 weeks prior to mating and to female rats 15 days prior to mating until 20 days post coitum at doses up to 100 mg/kg/day had no effect on fertility.

Pregnancy

Fluticasone propionate

Subcutaneous administration of fluticasone propionate to mice (150 micrograms/kg/day), rats (100 micrograms/kg/day) or rabbits (300 micrograms/kg/day) during pregnancy produced foetal abnormalities including cleft palate. Oral administration did not produce foetal abnormalities, consistent with the low bioavailability of fluticasone propionate by the oral route.

Mupirocin

In embryo-foetal development studies in rats there was no evidence of developmental toxicity at subcutaneous doses up to 375 mg/kg/day.

In an embryo-foetal development study in rabbits at subcutaneous doses up to 160 mg/kg/day, maternal toxicity (impaired weight gain and severe injection site irritation) at the high dose resulted in abortion or poor litter performance. However, there was no evidence of developmental toxicity in foetuses of rabbits maintaining pregnancy to term.

7. DESCRIPTION

Ointment

Micronised Fluticasone Propionate
Contains :

Fluticasone Propionate I.P.	0.005 % w/w
Mupirocin I.P.	2.0 % w/w

in a water soluble Ointment base

List of Excipients

Polyethylene Glycol 400, PEG 3350.

8. PHARMACEUTICAL PARTICULARS

8.1 Incompatibilities

No incompatibilities have been identified.

8.2 Shelf-Life

The expiry date is indicated on the label and packaging.

8.3 Packaging Information

Aluminium tube in a carton.

8.4 Storage and Handling Information

For External Use only. Wash your hands after application.

Store at temperature not exceeding 25º C. Do not freeze.

Keep out of reach of children.

Any product remaining at the end of treatment should be discarded.

Do not accept if tagger on tube nozzle is broken. Use the built-in pin on the cap to pierce the tagger.

9. PATIENT COUNSELLING INFORMATION

Registered Medical Practitioners may counsel their patients (and/or patients' caregivers as applicable) about the special warnings and precautions for use, drug interactions, undesirable effects, and any relevant contra-indications of *FLUTIBACT SKIN OINTMENT*. Patients (and/or their patients' caregiver) may also be informed about posology, method of administration and storage/handling information as applicable.

10. DETAILS OF MANUFACTURER

The Manufacturing Site details are mentioned on the label and packaging.

For further information please contact:
GlaxoSmithKline Pharmaceuticals Limited.
Registered Office
Dr. Annie Besant Road, Worli
Mumbai 400 030, India.

11. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE

Manufacturing License number is indicated on the label and packaging

12. DATE OF REVISION

01-SEP-2025

Trademarks are owned by or licensed to the GSK group of companies.

Version: FLT/PI/IN/2025/01

Adapted from

- *Fluticasone Propionate (Topical formulations) GDS v 15 dated 26 Mar 2020.*
- *Mupirocin GDS v19 dated 28 April 2025.*