

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

T-BACT CREAM

1. GENERIC NAME

Mupirocin Cream USP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains:

Mupirocin Calcium USP equivalent to Mupirocin	2.0 % w/w
Benzyl Alcohol I.P. (as Preservative)	1.0 % w/w
2-Phenoxyethanol I.P. (as Preservative)	0.5 % w/w

in a non-greasy base

List of Excipients

Benzyl Alcohol, 2-Phenoxyethanol, Xanthan gum, Liquid paraffin, Cetomacrogol, Stearyl alcohol, Cetyl alcohol, Purified water.

3. DOSAGE FORM AND STRENGTH

Cream

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

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication

T-BACT CREAM is indicated for the topical treatment of secondarily infected traumatic lesions such as small lacerations, sutured wounds or abrasions.

4.2 Posology and Method of Administration

Method of Administration:

A small quantity of *T-BACT CREAM* should be applied to the affected area with a piece of clean cotton wool or gauze swab.

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 cream.

Populations:

Adults/Children/Elderly/Renally impaired/Hepatically impaired:

3 times a day for up to 10 days, depending on the response.

4.3 Contraindications

T-BACT CREAM should not be given to patients with a history of hypersensitivity to mupirocin or any of the constituents of the preparation.

4.4 Special Warnings and Precautions for Use

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

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

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.

T-BACT CREAM is not suitable for ophthalmic use and intranasal use.

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

4.5 Drug Interactions

No drug interactions have been identified.

4.6 Use in Special Populations

Fertility

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

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

Lactation

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

If a cracked nipple is to be treated, it should be thoroughly washed prior to breast feeding.

4.7 Effects on Ability to Drive and Use Machines

No adverse effects on the ability to drive or operate machinery have been identified.

4.8 Undesirable Effects

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common (greater than or equal to 1/10), common (greater than or equal to 1/100, less than 1/10), uncommon (greater than or equal to 1/1000, less than 1/100), rare (greater than or equal to 1/10,000, less than 1/1000), very rare (less than 1/10,000), including isolated reports.

Data from clinical trials was used to determine the frequency of very common to rare undesirable effects. 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.

Skin and subcutaneous tissue disorders:

Common: Cutaneous hypersensitivity reactions

4.9 Overdose

Symptoms and Signs

There is currently limited experience with overdosage of mupirocin.

Treatment

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 or as recommended by the national poisons centre, where available.

5. PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of Action

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

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 species¹
Haemophilus influenzae
Neisseria gonorrhoeae
Neisseria meningitidis
Moraxella catarrhalis
Pasteurella multocida

¹Clinical efficacy has been demonstrated for susceptible isolates in approved clinical indications.

²Including beta-lactamase producing strains and methicillin-resistant strains

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

Systemic absorption of mupirocin through intact human skin is low although it may occur through broken/diseased skin. However, clinical trials have shown that when given systemically, it is metabolised to the microbiologically inactive metabolite monic acid and rapidly excreted.

Distribution

No relevant information.

Metabolism

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

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 Special Precautions for Use*).

6. NONCLINICAL PROPERTIES

Carcinogenesis/Mutagenesis

Carcinogenesis

Carcinogenicity studies with mupirocin have not been conducted.

Genotoxicity

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

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

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

Cream.

Contains:

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List of Excipients

Benzyl Alcohol, 2-Phenoxyethanol, Xanthan gum, Liquid paraffin, Cetomacrogol, Stearyl alcohol, Cetyl alcohol, Purified water.

8. PHARMACEUTICAL PARTICULARS

8.1 Incompatibilities

There are no relevant data available.

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 Instructions

Keep out of reach of children.

Store protected from direct sunlight at a temperature not exceeding 25°C. Do not freeze.

For External Use only. Wash your hands after application.

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

9. PATIENT COUNSELLING INFORMATION

Registered Medical Practitioners may counsel their patients (and/or their patients' caregiver as applicable) about the special warnings and precautions for use, drug interactions, undesirable effects, and any relevant contraindications of *T-BACT CREAM*. Patients (and/or the 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

02-AUG-2023

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

Version: TBACT-N/PI/IN/2023/01

Adapted from: Mupirocin GDS v17 dated 10th April 2017