Information For the Use
FRADIOMYCIN SULPHATE 1% CREAM

Fradiomycin Cream

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Introduction

Fradiomycin Sulphate 1% Cream is a topical antibiotic used to treat bacterial skin infections. Fradiomycin, also known as framycetin, is an aminoglycoside antibiotic that effectively inhibits bacterial growth, making it useful for managing wounds, burns, ulcers, and other superficial infections.

This formulation is designed for external application, helping to prevent and control infections by eliminating bacteria that commonly infect the skin.

Pharmacological Properties

Mechanism of Action

Fradiomycin (Framycetin) works by binding to bacterial ribosomes, specifically the 30S subunit, thereby inhibiting protein synthesis. This disruption prevents bacteria from growing and multiplying, leading to bacterial cell death. It is effective against a broad spectrum of **Gram-positive** and **Gram-negative** bacteria, including:

- **Staphylococcus aureus**
- **Streptococcus pyogenes**
- **Escherichia coli (E. coli)**
- **Klebsiella species**
- **Pseudomonas aeruginosa (limited efficacy)**

By eliminating bacteria at the site of application, this cream helps promote wound healing and reduces the risk of secondary infections.

Indications & Uses

Fradiomycin Sulphate 1% Cream is primarily indicated for bacterial skin infections, including:

Primary Indications:

- **Infected Wounds & Cuts:** Prevents bacterial colonization in minor cuts, abrasions, and surgical wounds.
- **Burns & Ulcers:** Helps reduce bacterial load and supports faster healing.
- **Impetigo & Other Bacterial Dermatoses:** Effective against superficial skin infections caused by **Staphylococcus** and **Streptococcus** bacteria.
- **Secondary Infections in Skin Conditions:** Prevents bacterial infections in conditions like **eczema, dermatitis, and psoriasis**.
- **Boils & Abscesses:** Aids in treating localized bacterial infections with pus formation.

Off-Label Uses:

- **Post-Surgical Wound Care:** Occasionally used in minor surgical procedures to prevent infections.
- **Infected Acne Lesions:** Helps control bacterial overgrowth in inflamed acne.

Dosage & Administration

Application Guidelines:

- **Dosage:** Apply a thin layer of cream **2-3 times daily** or as directed by a healthcare provider.
- **Method:**
  - Clean the affected area with mild antiseptic or saline solution.
  - Gently pat dry before applying the cream.
  - Cover with a sterile dressing if necessary (especially for wounds and burns).
- **Duration:** Use for **5-7 days** unless otherwise advised by a doctor. Prolonged use should be avoided to prevent antibiotic resistance.

- **Missed Dose:** If a dose is missed, apply it as soon as possible. If it is close to the next application, skip the missed dose.

Special Considerations:

- For **external use only**; avoid contact with **eyes, mouth, and mucous membranes**.
- **Not for deep wounds or severe burns** without medical supervision.
- **Do not exceed recommended duration**, as prolonged use may lead to antibiotic resistance or fungal superinfection.

Drug Interactions

Although Fradiomycin is a topical antibiotic with minimal systemic absorption, interactions can still occur:

Potential Interactions:

- **Other Topical Antibiotics (Neomycin, Bacitracin):** May increase the risk of skin irritation or allergic reactions.
- **Systemic Aminoglycosides (Gentamicin, Amikacin):** Combined use may increase the risk of toxicity (ototoxicity and nephrotoxicity), though rare with topical application.
- **Corticosteroids (Hydrocortisone, Betamethasone):** When used together, prolonged application may mask infection symptoms.

Avoid Concurrent Use With:

- **Other Nephrotoxic or Ototoxic Drugs:** Such as **loop diuretics (Furosemide), NSAIDs, and Vancomycin**, which may increase toxicity risk in prolonged systemic exposure.

Precautions & Warnings

Contraindications:

- **Hypersensitivity to aminoglycosides:** Patients with a known allergy to Fradiomycin, Neomycin, or other aminoglycoside antibiotics should avoid use.
- **Severe or deep infections:** Not suitable for **deep wounds, puncture wounds, or severe burns** without medical supervision.
- **Ear Application in Perforated Eardrum:** Should not be used in patients with a perforated tympanic membrane, as aminoglycosides may cause **ototoxicity (hearing damage).**
- **Prolonged Use:** Extended application beyond the prescribed period can lead to antibiotic resistance and secondary fungal infections.

Use in Pregnancy & Lactation:

- **Pregnancy:** Generally considered safe for topical use, but prolonged application should be avoided.
- **Lactation:** Minimal systemic absorption reduces the risk of transmission through breast milk. However, **avoid applying on or near the breast area** while breastfeeding.

Side Effects

Fradiomycin Sulphate 1% Cream is well tolerated, but side effects may occur in some individuals:

Common Side Effects:

- Mild **skin irritation** (redness, itching, burning)
- Dryness or **peeling of skin**
- Sensitivity reactions (especially in prolonged use)

Rare but Serious Side Effects:

- **Allergic Reactions:** Rash, swelling, severe itching, or difficulty breathing (discontinue use immediately).
- **Superinfection:** Overgrowth of resistant bacteria or fungi, particularly with prolonged use.
- **Ototoxicity (Hearing Loss):** Rare but possible if used near the ear with a ruptured eardrum.

If severe side effects occur, discontinue use and consult a doctor.

Monitoring & Follow-Up

- If **symptoms do not improve within 5-7 days**, seek medical advice.
- **For chronic skin conditions (eczema, dermatitis),** monitor for prolonged irritation or secondary infections.
- Patients with a **history of aminoglycoside allergies** should undergo a patch test before applying the cream to a large area.

Storage & Handling

- **Storage Temperature:** Keep in a **cool, dry place (below 25°C)**.
- **Keep Away From Children:** Do not ingest or allow accidental contact with mucous membranes.
- **Check Expiry Date:** Do not use expired products, as antibiotic potency may decrease.

Conclusion

Fradiomycin Sulphate 1% Cream is a **broad-spectrum topical antibiotic** effective for bacterial skin infections, minor wounds, burns, and ulcers. It works by **inhibiting bacterial protein synthesis**, preventing infection spread and promoting healing.

Proper application, adherence to dosage guidelines, and monitoring for side effects ensure safe and effective treatment. While generally well tolerated, it should not be overused to prevent antibiotic resistance or superinfections. For severe or persistent infections, consultation with a healthcare provider is recommended.

Manufactured in India for:

Cafoli™ LIFECARE

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