

DECOMB

Cream

Composition

Each gram contains:

Gramicidin	0.25 mg
Neomycin (as sulphate)	2.50 mg
Nystatin	100,000 I.U.
Triamcinolone acetonide	1.00 mg

Action

Decomb combines the potent corticosteroid triamcinolone acetonide with the antifungal antibiotic nystatin and the wide spectrum antibacterial activity of neomycin and gramicidin.

Decomb reduces inflammation, relieves pruritis and combats or prevents monilial and bacterial infections.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings. Topical corticosteroids can be absorbed from normal intact skin, inflammation and/or other disease processes in the skin increase percutaneous absorption.

Nystatin and gramicidin are not absorbed from intact skin or mucous membranes.

Neomycin can be absorbed through inflamed skin. Once absorbed, it is rapidly excreted unchanged through the kidneys. The half-life is approximately 2 to 3 hours.

Microbiology

Nystatin acts by binding to sterols in the cell membrane of susceptible species resulting in a change in membrane permeability and the subsequent leakage of intracellular components. Nystatin exhibits no activity against bacteria, protozoa, or viruses.

Neomycin exerts its bacterial activity against a number of gram-negative organisms by inhibiting protein synthesis. It is not active against *Pseudomonas aeruginosa*, and resistant strains of gram-negative bacteria may develop.

Gramicidin exerts its antibacterial activity against many gram-positive organisms by altering cell membrane permeability.

Indications

Decomb is indicated for use in corticosteroid responsive dermatoses complicated or threatened by secondary monilial and/or bacterial infections, such as:

- Atopic dermatitis
- Seborrheic dermatitis
- Lichen simplex chronicus
- Psoriasis (particularly of the face and body folds)
- Allergic contact dermatitis

Decomb cream permits use in moist intertrigenous areas.

Contraindications

- Known hypersensitivity to the preparation.
- Topical corticosteroids are contraindicated in fungal infections, tuberculosis of the skin, vaccinia, varicella, and herpes simplex.
- This preparation should not be applied in the external auditory canal of patients with perforated ear drum. This preparation is not intended for ophthalmic use.

Warnings

Ototoxicity and nephrotoxicity have been reported with the topical use of neomycin. The likelihood of their occurrence may be increased if the patient is being concurrently treated with an aminoglycoside antibiotic.

Pregnancy

Category C

There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the embryo or fetus.

Infants born to mothers, who have been treated during pregnancy with large amounts of corticosteroids or for prolonged periods, should be observed carefully for signs of hypoadrenalism.

Nursing Mothers

It is not known whether topical application of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk. Therefore, caution should be exercised when topical corticosteroids are applied to nursing women.

Paediatric Use

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced Hypothalamic-pituitary-adrenal (HPA) axis suppression and Cushing's syndrome than mature patients, because of a larger skin surface area to body weight ratio. Therefore, application of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen.

Adverse Reactions

The following local adverse reactions have been reported infrequently and are listed in an approximate decreasing order of occurrence: burning, itching, and irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, and allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

It should be noted that these adverse reactions might occur more frequently with occlusive dressings, tight-fitting diapers or plastic pants.

Hypersensitivity to Nystatin is extremely uncommon. Sensitivity reactions following the topical use of gramicidin are rare.

Signs of a sensitivity reaction to neomycin may also appear, usually in the form of a low-grade reddening with swelling, dry scaling or itching, or simply as a failure to heal. During long-term use of neomycin containing preparations, periodic examination for such signs is recommended. If they occur, patients should be advised to discontinue treatment.

Allergic cross-reactions may occur that could prevent the future use of any or all of the following antibiotics for the treatment of infections: kanamycin, paromomycin, streptomycin and Gentamicin.

Precautions

If sensitization or irritation occurs, discontinue use.

If the sensitivity is attributed to the antibiotic component, the patient should avoid neomycin-containing preparations in the future.

When using neomycin-containing preparations to control secondary infection in chronic dermatomes, it should be borne in mind that the skin is more liable to become sensitive to other substances, including neomycin.

If local infection should continue or become severe, or in the presence of systemic infection, appropriate antimicrobial therapy should be instituted. If a favourable response is not obtained, the use of this preparation should be temporarily discontinued, until the infection has been controlled.

If extensive areas are treated or if the occlusive technique is used, the possibility exists of increased systemic absorption and suitable precautions will be required in patients with electrolyte imbalance, gastrointestinal disturbances, diabetes, myopathy, cataract, renal or hepatic impairment, osteoporosis, and hemorrhage.

As with other antibiotic-containing topical preparations, prolonged use may result in an overgrowth of non-susceptible fungi. Appropriate measures should be taken if this occurs.

Because of the concern of possible nephrotoxicity and ototoxicity associated with neomycin, this preparation should not be used over a wide area or for extended periods.

Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia and glucosuria in some patients.

Conditions that augment systemic absorption include the application of potent steroids, use over large surface areas, prolonged use, and the use of occlusive dressings, tight-fitting diapers and plastic pants. Such patients should be periodically evaluated for evidence of HPA axis suppression. This is performed using urinary free cortisol and adrenocorticotrophic hormone (ACTH) stimulation tests. If HPA axis suppression is noted, an attempt should be made either to reduce the frequency of application, or to substitute a less potent steroid. Recovery of the HPA axis function is generally prompt and complete upon discontinuation of the drug.

Application of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen.

Dosage and Administration

The cream should be applied 2-3 times daily, with or without occlusive dressing.

Presentation

Tube of 10 or 20 grams