

Revacomb

Cream & Ointment



Composition:

Each 1 g of Revacomb cream or ointment contains:

Triamcinolone Acetonide	1 mg.
Nystatin	100,000 IU.
Neomycin (as sulphate)	2.5 mg.
Gramicidin	0.25 mg.

Pharmacological Classification:

Anti-inflammatory steroid, Anti-fungal, Antibiotic.

Intended Use (Common Use of the Drug):

Treatment of inflammatory skin diseases resulting from complicated infections due to bacteria and/or Candida.

Mechanism of Action:

Revacomb has a rapid anti-inflammatory, anti-itching and anti-allergic effect due to its strong corticosteroid, triamcinolone acetonide. The synergistic action of neomycin and gramicidin provides a broad spectrum of gram-positive and gram-negative bacteria, including microorganisms responsible for most bacterial skin infections, in addition to effectiveness against a wide range of yeasts and fungi such as *Candida albicans*, which is due to the presence of nystatin.

Pharmacokinetics:

Revacomb is well absorbed through intact skin, the absorbed portion undergoes hepatic metabolism and is excreted via the kidneys.

Indications:

Use this medicine exactly as described in this leaflet or as directed by your doctor or pharmacist. Check with your doctor if you have any questions.

- Revacomb is indicated for the relief of corticosteroid-responsive inflammatory or pruritic dermatoses caused, threatened or complicated by infection due to bacteria and/or candida.
- The Cream is indicated for Pruritus ani and pruritus vulvae.
- Conditions most commonly infected include acute atopic dermatitis, exfoliative erythrodermas, neurodermatitis, nummular eczema, acute contact dermatitis, chronic eczema (except of lower leg), chronic familiar benign pemphigus and intertriginous lesions.

Contraindications:

This medicine should not be used if you are hypersensitive to the active substance or any of the excipients.

Revacomb is contraindicated as follows:

- In Patients who are hypersensitive to this drug or to any ingredient in the formulation.
- In Tuberculous and most viral lesions of the skin (including herpes simplex, vaccinia and varicella) and fungal skin lesions except candidiasis.
- In primary skin infections.
- For ophthalmic use.
- For application to the external auditory canal of patients with perforated eardrums or patients with otitis media.
- As Occlusive therapy in patients with atopic dermatitis.

Side Effects:

Like all medicines, this one can cause side effects, although not everyone experiences them.

- Skin side effects have been reported with the use of topical corticosteroids, such as: dryness, itching, burning, local irritation, skin atrophy, skin stretching, atrophy of subcutaneous tissue, folliculitis, acne rash, hirsutism, change in skin pigmentation and telangiectasia.
- Adrenal suppression has also been reported following topical corticosteroid therapy.
- Hypersensitivity reactions to neomycin, gramicidin, and nystatin have been reported. Systemic neomycin toxicity has occurred rarely following topical administration; tinnitus and deafness have also been reported.
- Overgrowth of non-susceptible organisms has occurred.

Inform your doctor or pharmacist if you experience any side effects not listed in this leaflet.

Warnings & Precautions:

- Patients should be advised to inform their physician of prior use of corticosteroids.

- Revacomb Cream and Ointment should not be used under closed dressings.
- Topical corticosteroids should be used with caution in patients with stasis dermatitis and other skin diseases associated with poor circulation.
- Prolonged use over large areas may lead to steroid withdrawal symptoms when use of the drug is discontinued.
- Due to the potential risk of nephrotoxicity and ototoxicity, avoid prolonged use or use of large amounts in the treatment of post-burn skin infections, tropic ulceration and other conditions when absorption of neomycin is possible.
- Topical corticosteroids should be used with caution in lesions near the eye.
- If local irritation or sensitivity occurs, Revacomb Cream and Ointment should be discontinued and appropriate treatment initiated.
- It is not recommended to use dressings with products containing anti-infective agents such as Revacomb.

Drug and Food Interactions:

Tell your doctor or pharmacist if you are using, have recently used or might use any other drugs, and for how long you will be using the drug.

There may be an interaction between Revacomb and Aldesleukin or Other topical (skin-applied) corticosteroids.

Pregnancy & Lactation & Fertility:

Pregnancy: The safety of topical corticosteroid preparations during pregnancy has not been established. The potential benefit when used during pregnancy must be weighed against the potential hazards to the fetus.

Lactation: It is not known whether Topical Corticosteroids are excreted in human milk. Topical Corticosteroids should not be used during lactation unless the potential benefit justifies the potential risk to the nursing infant.

Fertility: Its effect on fertility after topical application in humans has not been studied.

Effects on ability to drive and use machines:

Revacomb does not affect the ability to drive and use machines when applied topically.

Method of use:

- Revacomb for external use only.
- Use this drug exactly as your doctor or pharmacist has prescribed it. Ask your doctor if you are not sure.
- Recommended Dose: Apply a small quantity two or three times daily. Do not apply more than prescribed by physician.
- Inform your doctor or pharmacist if you forget to apply the cream or ointment and before stopping its use.

Overdoses/Toxicity/methods of treatment:

Symptoms: Percutaneous absorption of corticosteroids can occur, especially if used over a large area for prolonged periods of time. If large amounts of corticosteroids are absorbed, toxic effects may include mild reversible suppression of adrenal function, ecchymoses of the skin, peptic ulceration, hypertension, aggravation of infections, hirsutism, acne, edema and muscle weakness due to protein depletion. Prolonged use of large amounts of Revacomb would likely increase the absorption of neomycin which in turn would enhance the potential for nephrotoxicity and ototoxicity as well as ulceration.

Treatment: No specific antidote is available; treatment should be primarily symptomatic and administration of Revacomb discontinued.

Physical Properties:

Smooth, uniform, yellow cream, free from foreign matter.

Storage Conditions:

Keep out of reach of children.
Store at a temperature below 30° C.
Keep tube tightly closed.

Packaging:

Each Revacomb cream or ointment carton box contains Aluminium Tube of 20 g.

*A medication is a product which affects your health, and it's consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist experts in medicine, it's benefits and risks.
- Do not repeat the same prescription without consulting your doctor.
- KEEP THE MEDICATIONS OUT OF REACH OF CHILDREN
Council of Arab Health Ministers, Union of Arab Pharmacies

Reva Pharma for Pharmaceutical Industries - Idlib - Syria

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