Beclic-G Ointment

Betamethasone dipropionate Gentamicin as sulfate

بیکلیک۔جی آئینٹمنٹ

بیٹامیتھاسون ڈائیپروپیونیٹ۔جینٹامائیسن

Composition

Active substances:

Betamethasone dipropionate

Gentamicin (as sulfate)

Generic form and active substance per unit

Each gm contains:

Betamethasone as dipropionate 0.05%. Gentamicin (as sulfate) 0.1%.

Therapeutic indications: Beclic-G Cream is indicated for the relief of the inflammatory manifestations of corticosteroidresponsive dermatoses when complicated by secondary infections caused by organisms susceptible to gentamycin.

Beclic-G Ointment is indicated for topical treatment of dermatosis complicated by secondary infection caused by organisms sensitive to Gentamicin.

Posology and method of administration

Adolescents and Adults:

Apply a thin film to the affected skin areas twice daily and carefully rub in. Frequency of application should be determined by the physician according to the severity of the condition. For some patients, adequate maintenance therapy may be achieved with less frequent application. Duration of therapy varies depending upon the extent and location of disease and patient response. However, if clinical improvement is not achieved by two to three weeks, diagnosis should be reviewed.

Children 2 to 12 years old:

Apply a thin film to only the affected skin and carefully rub in. Apply a sufficient amount no more frequently than twice daily with at least 6-12 hours between applications. Application to face, neck, scalp, genitalia, rectal area, and skin flexures should be applied under medical supervision.

Limit treatment to no more than 5 to 7 days.

See "Special Warnings and precautions for use", and "Use in pediatric patients".

Contraindications

Hypersensitivity to the active substances or to any of the excipients used in the preparation as well as to aminoglycoside antibiotics (cross allergy to gentamicin).

Beclic-G should not be applied to mucous membranes, to the eyes or the area surrounding the eyes.

Special warning and precautions for use: If irritation or sensitization develops with the use of Beclic-G Cream or Ointment, treatment should be discontinued and appropriate therapy instituted.

When applied topically, systemic absorption of the active substances may be increased if Beclic-G is used extensively, particularly during prolonged use or if applied to damaged skin.

Use beneath occlusive dressings further increases systemic absorption. Under such conditions, undesirable effects, which are seen following systemic application of the active substances, may occur. In such cases, particular caution is recommended in paediatric use.

During concomitant systemic administration of aminoglycoside antibiotics, it should be remembered that, in cases of increased dermal absorption, a cumulative toxic effect (ototoxicity, nephrotoxicity) is possible.

In particular, a possible cross reaction with other aminoglycoside antibiotics should be taken into consideration.

During long-term treatment with preparations containing antibiotics, non-susceptible microorganisms may develop, in particular mycosis. In such an event, or at the onset of a superinfection, appropriate treatment should be instituted.

High-dose, extensive or occlusive application of potent or highly-potent corticosteroids should only take place under regular, medical supervision; particularly in regard to the suppression of endogenous corticosteroid production and a possible metabolic effect.

A period of 2-3 weeks' continuous treatment should preferably not be exceeded.

Highly-potent, potent and medium-dose corticosteroids should be used with caution in the facial and genital region; treatment should not exceed one week in such cases. Generally speaking, only low-dose corticosteroids should be used around the eyes (glaucoma).

Corticosteroids may mask the symptoms of an allergic skin reaction to one of the product ingredients.

The patient should be instructed to use the product solely in the treatment of his/her current skin condition, and not to pass it on to others.

Use in paediatric patients:

Use of this product in pediatric patients younger than 2 years of age is not recommended. When compared with adults, paediatric patients may demonstrate greater susceptibility to hypothalamicpituitary- adrenal (HPA) axis suppression (induced by topical corticosteroids) and to exogenous corticosteroid effects, as absorption in children is greater due to the higher skin surface area to body weight ratio.

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain and intracranial hypertension have been reported in children receiving topical corticosteroids.

Symptoms of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Symptoms of intracranial hypertension include bulging fontanelles, headache and bilateral papilledema.

Interactions: When Beclic-G is used in the genital or anal region, the presence of petroleum jelly and liquid paraffin (excipients used in the product) may diminish the tear resistance of concomitantly used latex condoms, thereby compromising their safety when in use.

Pregnancy, lactation

Pregnancy: In animal studies, topical application of corticosteroids was shown to have a teratogenic effect.

There are no data on its use in human pregnancies.

Aminoglycosides cross the placental barrier and may harm the fetus if administered to pregnant women. There have been reports of total, irreversible, bilateral, congenital deafness in infants whose mothers received aminoglycosides (including gentamicin) during pregnancy. Sufficient data on the use of topically applied gentamicin during pregnancy is lacking.

During pregnancy, Beclic-G should only be used in cases where it is absolutely necessary.

Lactation: It is not known whether topically applied corticosteroids pass into breast milk. However, systemically available corticosteroids are excreted in breast milk.

It is not known whether gentamicin passes into breast milk. If applied to the breasts, Beclic-G may not be used by nursing mothers.

Effects on ability to drive machines: The effect on the ability to drive and operate machinery has not been studied.

Undesirable effects

Initiation of treatment

Skin: Rare: irritations, burning sensations, pruritus, skin dryness, hypersensitivity reactions to one of the ingredients used in the product and skin discoloration.

Extensive, occlusive and/or prolonged use

During extensive, occlusive and/or prolonged use, local skin changes may occur. During extensive use, systemic effects (adrenal suppression) may occur.

It should be remembered that patients are at greater risk of developing secondary infections as a result of diminished local resistance to infection.

Skin
Localised skin changes such as atrophy (particularly facial), telangiectasia, striae, striae distensae, cutaneous bleeding, purpura, steroid acne, rosacea-like/ perioral dermatitis and hypertrichosis, skin discoloration. It is not known whether the skin discoloration is reversible.
Uncommon: contact sensitisation to gentamicin.
Rare: skin irritation (erythema, pruritus)
Possible photosensitisation was observed in some patients, however, it was impossible to reproduce this effect when gentamicin was reapplied, with subsequent exposure to UV radiation.
Endocrine system
Endogenous corticosteroid synthesis suppression; overactive adrenal glands with oedema.
Metabolism
Manifestation of latent diabetes mellitus.
Ear, inner ear/ renal In cases of concomitant systemic administration of aminoglycoside antibiotics, cumulative ototoxicity/ nephrotoxicity can is possible if Beclic-G is used extensively or on damaged skin.
Musculoskeletal system
Osteoporosis, growth retardation (in children).
Overdose
Symptoms: Excessive or prolonged use of topical corticosteroids may lead to a suppression of the pituitary-adrenal function, and may cause secondary adrenal insufficiency and symptoms of adrenal cortex hyperactivity, including Cushing's syndrome.
It cannot be excluded that a single excessive dose of gentamicin might induce such symptoms.
Excessive and prolonged use of topically applied gentamicin may lead to an increased growth of fungi or non-susceptible bacteria at the site of skin lesions.
Treatment: Appropriate symptomatic treatment is indicated. Acute symptoms of adrenal cortex hyperactivity are usually reversible. Electrolyte imbalances should be treated where required. In cases of chronic toxicity, withdrawal of corticosteroids should be gradual.
If overgrowth by non-susceptible organisms occurs, stop treatment with Beclic-G Cream or Ointment and institute appropriate antimycotic or antibacterial treatment.
Mechanism of action
Beclic-G combines the antibacterial action of gentamicin (an aminoglycoside antibiotic) with the anti-inflammatory, antipruritic and vasoconstrictive properties of betamethasone dipropionate (a highly potent, class III corticosteroid).
Gentamicin interferes with the growth of sensitive bacteria by inhibiting protein synthesis. Its action against pathogenic, Gram-negative and Gram-positive bacteria is bactericidal, and is based on the ability of the antibiotic to bind to bacterial 30S ribosomal subunits.
In the table below, bacteria are categorised according to their susceptibility to gentamicin:
The following bacteria are usually resistant to aminoglycosides: meningococci, *Streptococcus pneumoniae*, most types of streptococci (notably Group D), *Mycoplasma* sp., *Chlamydia* sp. and anaerobes such as *Bacteroides* sp. and *Clostridium* sp.
Inflamed skin diseases due to secondary bacterial infections can be treated with Beclic-G, bringing relief from subjective complaints such as pruritus.
The ointment is particularly suitable for use on dry and chapped skin.
The cream is a cooling, non-oily, water-permeable oil-in-water emulsion, which is indicated for acute and weeping stages of disease.
Pharmacokinetics: No penetration or absorption studies have been performed on this generic formulation. Under normal circumstances, only a fraction of the locally applied amount of corticosteroid is systemically available. Penetration and permeation rates depend on the body site, skin condition, the generic formulation being used, patient age and method of application.
Gentamicin absorption need hardly be considered when used on intact skin. However, increased percutaneous absorption should be taken into account in cases of keratin layer loss, inflammation and occlusive/ extensive application. When used topically, absorption may be greater with the cream formulation when compared with the ointment.
Preclinical data
Betamethasone:
Corticosteroid studies using animal models have shown that betamethasone is toxic to reproduction (cleft palate, skeletal malformations).
In reproduction toxicity studies on rats, prolonged gestation, prolonged labour and dystocia were recorded. Furthermore, a reduction in offspring survival was observed, as well as decreased body weight and a reduction in weight gain. There was no evidence of impaired fertility.
Mutagenicity and carcinogenicity have not been studied.
Gentamicin
Toxicity studies on animals and humans have not yielded any evidence of skin irritation, following local application of twice-daily gentamicin over three days at concentrations several times higher than those in formulations for therapeutic use.
Results from epicutaneous Draize patch tests (conducted on 100 patients) have demonstrated that gentamicin is not a primary skin irritant. Furthermore, gentamicin has a low skin sensitisation index.
Mutagenicity and carcinogenicity have not been studied.
Further information
Beclic-G should not be used after the expiry date, which is stated on the package/ tube after "EXP".
Storage conditions
Store at room temperature. After first opening, can be used up to 3 months.
Keep out of the reach and sight of children
Nature and contents of container
Beclic-G Ointment 15 g.

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