210.00 mm

140.00 mm

Betasol Lotion
(Betamethasone Dipropionate)

Betasol-S Lotion
(Betamethasone dipropionate + Salicylic acid)

Betasol-C Oinment
(Betamethasone dipropionate + Calcipotriol monohydrate)

Betasol-N Cream
(Betamethasone valerate + Neomycin sulphate)

Betasol-G Cream
(Betamethasone dipropionate + Gentamycin sulphate)

Betasol-G Oinment
(Betamethasone dipropionate + Gentamycin sulphate)

بیٹاسول لوشن
(بیٹامیتھاسون ڈائی پروپاؤنیٹ)

بیٹاسول-ایس لوشن
(بیٹامیتھاسون ڈائی پروپاؤنیٹ+سیلیسیلک ایسڈ)

بیٹاسول-سی آئنٹمنٹ
(بیٹامیتھاسون ڈائی پروپاؤنیٹ+کیلسپٹرائیول مونوہائیڈریٹ)

بیٹاسول-این کریم
(بیٹامیتھاسون ویلیریٹ+نیومائسین سلفیٹ)

بیٹاسول-جی کریم
(بیٹامیتھاسون ڈائی پروپاؤنیٹ+جینٹامائسن سلفیٹ)

بیٹاسول-جی آئنٹمنٹ
(بیٹامیتھاسون ڈائی پروپاؤنیٹ+جینٹامائسن سلفیٹ)

COMPOSITION:

Betasol Lotion
Each gram contains:
Betamethasone as dipropionate 0.5mg
(USP Specifications)

Betasol-S Lotion
Each gram contains:
Betamethasone as dipropionate 0.5mg
Salicylic acid.....20mg
(Innovator's Specifications)

Betasol-C Ointment
Each gram contains:
Betamethasone as dipropionate 0.5mg
Calcipotriol as monohydrate.....50mcg
(BP Specifications)

Betasol-G Ointment 0.05% w/w +0.1% w/w
Each gram contains:
Betamethasone as dipropionate.....0.5mg
Gentamycin as sulphate.....1mg
(Innovator's Specifications)

Betasol-G Cream 0.05% w/w + 0.1% w/w
Each gram contains:
Betamethasone as dipropionate.....0.5mg
Gentamycin as sulphate.....1mg
(Innovator's Specifications)

Betasol-N Cream
Each gram contains:
Betamethasone (as valerate).....1mg
Neomycin sulphate 5mg
(Innovator's Specifications)

DESCRIPTION:
Betamethasone, a synthetic adrenocorticosteroid, for topical use.

Betamethasone is an analog of prednisolone, has a high degree of corticosteroid activity and a slight degree of mineralocorticoid activity. It is active topically and produces a rapid and sustained response in those inflammatory dermatoses that are normally responsive to topical corticosteroid therapy, and it is also effective in the less responsive conditions, such as psoriasis of the scalp.

Salicylic acid is a keratolytic and antiseptic agent. Topical salicylic acid softens keratin, loosens cornified epithelium and desquamates the epidermis

Calcipotriol, also known as calcipotriene, is a synthetic derivative of calcitriol, a from of vitamin D. It used in the treatment of psoriasis.

Gentamicin Sulfate is a wide spectrum antibiotic that provides highly effective topical treatment in primary and secondary bacterial infections of the skin. This product may clear infections that have not responded to other topical antibiotic agents.

Neomycin sulfate is a type of anti-infective medicine. It fights bacterial infections of the skin.

MECHANISM OF ACTION:

Betasol/Betasol-S lotion contains the dipropionate ester of betamethasone which is a glucocorticoid exhibiting the general properties of corticosteroids, and salicylic acid which has keratolytic properties. Salicylic acid is applied topically in the treatment of hyperkeratotic and scaling conditions where its keratolytic action facilitates penetration of the corticosteroid. Betamethasone dipropionate with salicylic acid combines the anti-inflammatory, antipruritic and vasoconstrictive activity of betamethasone dipropionate with the keratolytic effects of salicylic acid.

Betasol-G ointment/cream combines the sustained anti-inflammatory, antipruritic and vasoconstrictive actions of betamethasone dipropionate with the wide-spectrum bactericidal antibiotic activity of gentamicin sulfate. Gentamicin, a wide spectrum bactericidal antibiotic, is effective against a broad spectrum of common skin pathogens. Bacteria susceptible to gentamicin include sensitive strains of Staphylococcus aureus (coagulase positive, coagulase negative and some penicillinase-producing strains), and the gram-negative bacteria: Pseudomonas aeruginosa, Aerobacter aerogenes, Escherichia coli, Proteus vulgaris and Klebsiella pneumoniae.

Betasol-C ointment combines the sustained anti-inflammatory, antipruritic and vasoconstrictive actions of betamethasone dipropionate with calcipotriol, a vitamin D analogue. In vitro data suggests that calcipotriol induces differentiation and suppresses proliferation of keratinocytes. This is the proposed basis for its effect in psoriasis. In pharmacological doses, corticosteroids are used primarily for their anti-inflammatory and/or immune suppressive effects. Topical corticosteroids such as betamethasone dipropionate are effective in the treatment of a range of dermatoses because of their anti-inflammatory, anti-pruritic and vasoconstrictive actions. However, while the physiologic, pharmacologic and clinical effects of the corticosteroids are well known, the exact mechanisms of their action in each disease are uncertain.

Betasol-N cream combines the effect of Betamethasone valerate and neomycin sulphate. Betamethasone is an active corticosteroid that produces a satisfactory response in those inflammatory dermatoses that are normally responsive to topical corticosteroid therapy, and is often effective in the less responsive conditions such as psoriasis. Neomycin sulphate is a broad spectrum, bactericidal antibiotic effective against the majority of bacteria commonly associated with skin infections.

INDICATIONS:

Betasol lotion is indicated for eczema and dermatitis of all types affecting the scalp including atopic eczema, photodermatitis, primary irritant and allergic dermatitis, lichen planus, lichen simplex, discoid lupus erythematosus, erythroderma.
It is also indicated for psoriasis of the scalp.

Betasol-S lotion is indicated for the treatment of hyperkeratotic and dry corticosteroid-responsive dermatoses where the cornified epithelium may resist penetration of the steroid. The salicylic acid constituent of lotion, as a result of its descaling action, allows access of the dermis more rapidly than by applying steroid alone.

Betasol-G ointment/cream is indicated for the relief of the inflammatory manifestations of corticosteroid responsive dermatoses when complicated by secondary infection, caused by organisms susceptible to gentamicin or when the possibility of such infections is suspected. Such disorders include: psoriasis, contact dermatitis (dermatitis venenata), atopic dermatitis (infantile eczema, allergic dermatitis), neurodermatitis (lichen simplex chronicus), lichen planus, eczema (including nummular eczema, hand eczema, eczematous dermatitis), intertrigo, dyshidrosis (pompholyx), seborrheic dermatitis, exfoliative dermatitis, solar dermatitis, stasis dermatitis, and anogenital and senile pruritus.

Betasol-C ointment is indicated for the topical treatment of stable plaque psoriasis vulgaris amenable to topical therapy in adults.

Betasol-N cream is indicated in the management of corticosteroid sensitive dermatoses actually or potentially complicated by infection due to micro-organisms sensitive to the anti-infective contained therein. It is indicated for the treatment of the following conditions where secondary bacterial infection is present, suspected or likely to occur: eczema, including atopic, infantile, discoid eczemas; prurigo nodularis; psoriasis (excluding widespread plaque psoriasis); neurodermatoses, including lichen simplex; lichen planus; seborrhoeic dermatitis; contact sensitivity reactions, insect bite reactions, prickly heat, anal and genital intertrigo, and otitis externa.

DOSAGE & ADMINISTRATION:

Betasol lotion: A few drops of Betasol Lotion should be applied to the affected areas twice daily and massaged gently and thoroughly into the affected area. For some patients adequate maintenance therapy may be achieved with less frequent application.

Betasol-S lotion:

Adults: Once to twice daily. In most cases a thin film should be applied to the affected areas twice daily and massaged gently and thoroughly into the skin.
For some patients adequate maintenance therapy may be achieved with less frequent application.
It is recommended that Betasol-S lotion are prescribed for two weeks, and that treatment is reviewed at that time. The maximum weekly dose should not exceed 60 g.

Children: Dosage in children should be limited to 5 days.

Betasol-G ointment/cream: A thin film of Betasol-G ointment or cream should be applied to cover completely the affected area twice daily, in the morning and at night. 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 three to four weeks, diagnosis should be reviewed.

Betasol-C ointment: It should be applied to the affected area once daily. The recommended treatment period is 4 weeks. There is experience with repeated courses of Calcipotriol / Betamethasone up to 52 weeks. If it is necessary to continue or restart treatment after 4 weeks, treatment should be continued after medical review and under regular medical supervision. When using calcipotriol containing medicinal products, the maximum daily dose should not exceed 15 g. The body surface area treated with calcipotriol containing medicinal products should not exceed 30 %. Calcipotriol /Betamethasone ointment should be applied to the affected area. In order to achieve optimal effect, it is not recommended to take a shower or bath immediately after application of Calcipotriol / Betamethasone ointment.

Betasol-N cream A small quantity should be applied to the affected area one to three times daily until improvement occurs or as directed by a physician. It may then be possible to maintain improvement by applying once a day or even less often. Betasol-N Cream is especially appropriate for moist or weeping surfaces. In the more resistant lesions, such as the thickened plaques of psoriasis on elbows and knees, the effect of Betasol-N can be enhanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response in such lesions. Thereafter, improvement can usually be maintained by regular application without occlusion. Treatment should not be continued for more than 7 days without medical supervision. Betasol-N is suitable for use in children (2 years and over) at the same dose as adults. A possibility of increased absorption existing in very young children, thus

Betasol-N is not recommended for use in neonates and infants.

PHARMACOKINETICS:

Salicylic acid exerts only local action after topical application. The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of the epidermal barrier and the use of occlusive dressings. Topical corticosteroids can be absorbed through intact, normal skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Once absorbed through the skin, topical corticosteroids enter pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees, are metabolised primarily in the liver and excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted in the bile.

PRECAUTIONS:

Occlusion must not be used, since under these circumstances the keratolytic action of salicylic acid may lead to enhanced absorption of the steroid. Local and systemic toxicity is common, especially following long continuous use on large areas of damaged skin, in flexures or with polythene occlusion. If used in children or on the face courses should be limited to 5 days. Long term continuous therapy should be avoided in all patients irrespective of age. Topical corticosteroids may be hazardous in psoriasis for a number of reasons, including rebound relapses following development of tolerance, risk of generalized pustular psoriasis and local systemic toxicity due to impaired barrier function of the skin. Careful patient supervision is important. It is dangerous if betamethasone preparations come into contact with the eyes. Avoid contact with the eyes and mucous membranes. The systemic absorption of betamethasone dipropionate and salicylic acid may be increased if extensive body surface areas or skin folds are treated for prolonged periods or with excessive amounts of steroids. Suitable precautions should be taken in these circumstances, particularly with infants and children. If irritation or sensitisation develops with the use of betamethasone preparations, treatment should be discontinued. Any side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children. If excessive dryness or increased skin irritation develops, discontinue use of this preparation. Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes of visual disturbances which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids. Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome also can be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid. Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children. Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios. Calcipotriol / Betamethasone ointment contains a potent group III steroid and concurrent treatment with other steroids must be avoided. In a study in patients with both extensive scalp and extensive body psoriasis using a combination of high doses of Calcipotriol/Betamethasone gel (scalp application) and high doses of Calcipotriol / Betamethasone ointment (body application), 5 of 32 patients showed a borderline decrease in cortisol response to adrenocorticotropic hormone (ACTH) challenge after 4 weeks of treatment. Due to the content of calcipotriol, hypercalcaemia may occur if the maximum daily dose (15 g) is exceeded. Serum calcium is normalised when treatment is discontinued. The risk of hypercalcaemia is minimal when the recommendations relevant to calcipotriol are followed. Treatment of more than 30 % of the body surface should be avoided. Calcipotriol/Betamethasone contains a potent group III-steroid and concurrent treatment with other steroids on the same treatment area must be avoided. Skin of the face and genitals are very sensitive to corticosteroids. The medicinal product should not be used in these areas. The patient must be instructed in correct use of the medicinal product to avoid application and accidental transfer to the face, mouth and eyes. Hands must be washed after each application to avoid accidental transfer to these areas.

Cross-allergenicity among aminoglycosides has been demonstrated. Systemic absorption of topically applied gentamicin may be increased if extensive body surface areas are treated, especially over prolonged time periods or in the presence of dermal disruption. In these cases, the undesirable effects which occur following systemic use of gentamicin may potentially occur. Cautious use is recommended under these conditions, particularly in infants and children. Prolonged use of topical antibiotics occasionally allows overgrowth of non-susceptible organisms, including fungi. If this occurs, or if irritation, sensitization or superinfection develops, treatment with gentamicin should be discontinued and appropriate therapy instituted. Following significant systemic absorption, aminoglycosides such as neomycin, gentamycin can cause irreversible ototoxicity: and neomycin has nephrotoxic potential. In renal impairment the plasma clearance of neomycin is reduced.

Pregnancy & Lactation

Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively in large amounts or for prolonged periods of time in pregnant patients. Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

SIDE EFFECTS:

Betasol/Betasol-S lotion/ Betasol-G ointment/cream: Continuous application without interruption may result in local atrophy of the skin, striae and superficial vascular dilation, particularly on the face. Adverse reactions to Betasol-G ointment/cream have been reported very rarely and include hypersensitivity and skin discoloration. Treatment with gentamicin has produced transient irritation (erythema and pruritus) that usually did not require discontinuance of treatment. Adverse reactions that have been reported with the use of topical corticosteroids include: Burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis and allergic contact dermatitis. The following may occur more frequently with the use of occlusive dressings: maceration of the skin, secondary infection, skin atrophy, striae and miliaria. Vision blurred has been reported with corticosteroid use (frequency not known). In addition, prolonged use of salicylic acid preparations may cause dermatitis.

Betasol-C ointment: Adverse reactions include application site reactions, pruritus, skin irritation, burning and stinging sensation, dry skin, erythema, rash, dermatitis, eczema, psoriasis aggravated, photosensitivity and hypersensitivity reactions including very rare cases of angioedema and facial edema. Systemic effects after topical use may appear very rarely causing hypercalcaemia or hypercalciuria. Local reactions can occur after topical use, especially during prolonged application, including skin atrophy, telangiectasia, striae, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, de-pigmentation and colloid milia. When treating psoriasis with topical corticosteroids there may be a risk of generalised pustular psoriasis. Systemic reactions due to topical use of corticosteroids are rare in adults, however they can be severe. Adrenocortical suppression, cataract, infections, impact on the metabolic control of diabetes mellitus and increase of intra-ocular pressure can occur, especially after long term treatment. Systemic reactions occur more frequently when applied under occlusion (plastic, skin folds), when applied on large areas and during long term treatment

Betasol-N cream: There are reports of local skin burning, pruritis, pigmentation changes, hypertrichosis and allergic contact dermatitis with topical steroids. Exacerbation of symptoms may occur. As with other topical corticosteroids, prolonged use of large amounts, or treatment of extensive areas, can result in sufficient systemic absorption to produce the features of hypercortisolism. The effect is more likely to occur in infants and children, and if occlusive dressing are used. In infants, the napkin may act as an occlusive dressing. In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the putsular form of the disease. This cream is usually well tolerated, but if signs of hypersensitivity appear, application should stop immediately.

CONTRAINDICATIONS:

Hypersensitivity to the active substances or to any of the excipients. Calcipotriol/Betamethasone ointment is contraindicated in erythrodermic, exfoliative and pustular psoriasis, with known disorders of calcium metabolism. Due to the content of corticosteroid in all preparations, contraindicated in the following conditions:

Acne vulgaris, acne rosacea, rosacea perioral dermatitis, perianal and particularly herpes simplex, vacinia, varicella. Napkin eruptions, fungal or bacterial skin infections without suitable concomitant anti-infective therapy. Preparations containing neomycin should not be used for the treatment of otitis externa when the ear drum is perforated, because of the risk of ototoxicity. Due to the known ototoxic and nephrotoxic potential of neomycin sulphate, the use of Betasol-N in large quantities or on large areas for prolonged periods of time is not recommended in circumstances where significant systemic absorption may occur. A possibility of increased absorption exists in very young children, thus Betasol-N is not recommended for use in neonates and infants (up to 2 years). In neonates and infants, absorption by immature skin may be enhanced, and renal function may be immature.

STORAGE & INSTRUCTIONS:

Storage temperature for:

Betasol-C Ointment, Betasol-G Ointment, Betasol-G Cream & Betasol-N Cream: 15-30°C.

Betasol Lotion & Betasol-S Lotion: 15-25°C.

Protect from heat, sunlight and moisture. Do not freeze or refrigerate. Keep away from the reach of children.

To be sold on the prescription of a registered medical practitioner only.

FOR EXTERNAL USE ONLY.

HOW SUPPLIED:

Betasol Lotion: 20ml in Plastic Bottle.
Betasol-S Lotion: 20ml in Plastic Bottle.
Betasol-C Ointment: 15g Tube
Betasol-G Ointment 0.05% w/w +0.1% w/w: 15g Tube
Betasol-G Cream 0.05% w/w +0.1% w/w: 15g Tube
Betasol-N cream: 15g Tube

خوراک وطریقہ استعمال:

ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

ہدایات:

بیٹا سول لوشن اور بیٹا سول۔ ایس لوشن کو ۱۵۔۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔ بیٹا سول۔سی آئنٹمنٹ، بیٹا سول۔جی آئنٹمنٹ، بیٹا سول۔جی کریم اور بیٹا سول۔این کریم کو ۱۵۔۳۰ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔ دھوپ، گرمی، نمی اور منجمد ہونے سے بچائیں۔ ریفریجریٹر میں نہ رکھیں۔ بچوں کی پہنچ سے دور رکھیں۔ صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔ صرف بیرونی استعمال کے لئے ہے۔

Manufactured by:
PHARMASOL
PRIVATE LIMITED
Plot # 549,Sundar Industrial Estate,
Lahore, Pakistan.