

Axtriol-B GEL - PIL

Size: W5”x H7”



Axtriol-B Gel

NAME AND STRENGTH OF ACTIVE SUBSTANCES :

Calcipotriol (as Monohydrate) 50 mcg/g and Betamethasone (as Dipropionate) 0.5mg/g

PRODUCT DESCRIPTION: A translucent off-white viscous gel with characteristic odour.

Other excipients are Liquid Paraffin, Polyoxy Propylene Stearyl Ether, Hydrogenated Castor Oil, All-rac-Alpha-Tocopherol and Butylated Hydroxytoluene.

PHARMACODYNAMICS: Calcipotriol is a vitamin D analogue. Calcipotriol induces differentiation and suppresses proliferation of keratinocytes. This is the proposed basis for its effect in psoriasis.

Like other topical corticosteroids, Betamethasone Dipropionate has anti-inflammatory, antipruritic, vasoconstrictive and immunosuppressive properties, however, without curing the underlying condition. Through occlusion the effect can be enhanced due to increased penetration of the stratum corneum. The incidence of adverse events will increase because of this. In general, the mechanism of the anti-inflammatory activity of the topical steroids is unclear.

PHARMACOKINETICS: Application to psoriasis plaques and under occlusive dressings may increase the absorption of topical corticosteroids. Following systematic exposure, both active ingredients-calcipotriol and betamethasone dipropionate- are rapidly and extensively metabolised. One metabolite of calcipotriol and one metabolite of betamethasone dipropionate were quantifiable in some of the patients.

INDICATIONS: Topical treatment of scalp and non-scalp plaque psoriasis vulgaris in adults.

CONTRAINDICATIONS: Hypersensitivity to the active substances or to any of the excipients.

Due to the content of Calcipotriol, Axtriol-B Gel contraindicated in patients with known disorders of calcium metabolism.

Due to the content of corticosteroid, Axtriol-B Gel is contraindicated in the following conditions: Viral (e.g. herpes or varicella) lesions of the skin, fungal or bacterial skin infections, parasitic infections, skin manifestations in relation to tuberculosis, perioral dermatitis, atrophic skin, striae atrophicae, fragility of skin veins, ichthyosis, acne vulgaris, acne rosacea, rosacea, ulcers and wounds.

Axtriol-B Gel is contraindicated in erythrodermic, exfoliative and pustular psoriasis.

ADVERSE EFFECTS/UNDESIRABLE EFFECTS:

Infections and infestations	
Uncommon $\geq 1/1,000$ to $< 1/100$	Skin infection* Folliculitis
Immune system disorders	
Rare $\geq 1/10,000$ to $< 1/1,000$	Hypersensitivity
Eye disorders	
Uncommon $\geq 1/1,000$ to $< 1/100$	Eye irritation
Skin and subcutaneous tissue disorders	
Common $\geq 1/100$ to $< 1/10$	Pruritus
Uncommon $\geq 1/1,000$ to $< 1/100$	Exacerbation of psoriasis dermatitis Erythema Rash** Acne Skin burning sensation Skin irritation Dry skin
Rare $\geq 1/10,000$ to $< 1/1,000$	Skin striae Skin exfoliation
General disorders and administration site conditions	
Uncommon $\geq 1/1,000$ to $< 1/100$	Application site pain***
Rare $\geq 1/10,000$ to $< 1/1,000$	Rebound effect

*Skin infections including bacterial, fungal and viral skin infections have been reported.

** Various types of rash reactions such as rash erythematous and rash pustular have been reported.

***Application site burning is included in application site pain.

The following adverse reactions are considered to be related to the pharmacological classes of Calcipotriol and Betamethasone, respectively:

Calcipotriol: 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 oedema. Systemic effects after topical use may appear very rarely causing hypercalcaemia or hypercalciuria.

Betamethasone (as Dipropionate): Local reactions can occur after topical use, especially during prolonged application, including skin atrophy, telangiectasia, striae, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, depigmentation and colloid milia.

When treating psoriasis, 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.

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Systemic reactions occur more frequently when applied under occlusion (plastic, skin folds), when applied on large areas and during long-term treatment.

INTERACTION WITH OTHER MEDICAMENTS:
No interaction studies have been performed.

WARNING AND PRECAUTIONS

Concurrent treatment and UV exposure: Physicians are recommended to advise patients to limit or avoid excessive exposure to either natural or artificial sunlight. Topical calcipotriol should be used with UVR only if the physician and patient consider that the potential benefits outweigh the potential risks.

Adverse reactions to excipients: Axtriol-B Gel contains butylated hydroxytoluene as an excipient, which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Effects on endocrine system: Adverse reactions found in connection with systemic corticosteroid treatment, such as adrenocortical suppression or impact on the metabolic control of diabetes mellitus may occur also during topical corticosteroid treatment due to systemic absorption.

Application under occlusive dressings should be avoided since it increases the systemic absorption of corticosteroids. Application on large areas of damaged skin, or on mucous membranes or in skin folds should be avoided since it increases the systemic absorption of corticosteroids.

Effects on calcium metabolism: Due to the content of Calcipotriol, hypercalcaemia may occur if the maximum daily dose (15g) is exceeded. Serum calcium is normalised when treatment is discontinued. The risk of hypercalcaemia is minimal when the recommendations relevant to Calcipotriol are followed.

Local adverse reactions: Axtriol-B Gel contains a potent group III-steroid and concurrent treatment with other steroids 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 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.

Concomitant skin infections: When lesions become secondarily infected, they should be treated with antimicrobial therapy. However, if infection worsens, treatment with corticosteroids should be stopped.

Discontinuation of treatment: When treating psoriasis with topical corticosteroids, there may be a risk of generalised pustular psoriasis or of rebound effects when discontinuing treatment. Medical supervision should therefore continue in the post-treatment period.

Long-term use: With long-term use there is an increased risk of local and systemic corticosteroid adverse reactions. The treatment should be discontinued in case of adverse reactions related to long-term use of corticosteroid.

Unevaluated use: There is no experience with the use of Axtriol-B Gel in guttate psoriasis.

PREGNANCY AND LACTATION

Pregnancy: There are no data from the use of Calcipotriol and Betamethasone Dipropionate in pregnant women. In general, the use of topical preparations containing glucocorticoids should be avoided during the first trimester of pregnancy. In particular, treating large areas, prolonged use or occlusive dressing should be avoided during pregnancy. Thus, the clinical indication for treatment with Axtriol-B Gel must be carefully reviewed and the benefits weighed against the risks in pregnant women.

Lactation: Betamethasone passes into breast milk, but risk of an adverse effect on the infant seems unlikely with therapeutic doses. There are no data on the excretion of Calcipotriol in breast milk. Caution should be exercised when prescribing Axtriol-B Gel to women who breast-feed. The patient should be instructed not to use Axtriol-B Gel on the breast when breastfeeding.

ROUTE OF ADMINISTRATION: Topical

RECOMMENDED DOSAGE: Axtriol-B Gel should be applied to affected areas once daily. The recommended treatment period is 4 weeks for scalp areas and 8 weeks for "non-scalp" areas. If it is necessary to continue or restart treatment after this period, 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 15g. The body surface area treated with calcipotriol containing medicinal products should not exceed 30%.

If used on the scalp: All the affected scalp areas may be treated with Axtriol-B Gel. Usually an amount between 1 g and 4 g per day is sufficient for treatment of the scalp (4 g corresponds to one teaspoon).

Special Populations:

Renal and hepatic impairment

The safety and efficacy of Axtriol-B Gel in patients with severe renal insufficiency or severe hepatic disorders have not been evaluated.

Paediatric population

The safety and efficacy of Axtriol-B Gel in children below 18 years have not been established. In children aged 12 to 17 years, no recommendation on a posology can be made.

INSTRUCTION FOR USE

Method of administration

For topical use only.

Axtriol-B Gel should not be applied directly to the face or eyes. In order to achieve optimal effect, it is not recommended to take a shower or bath, or to wash the hair in case of scalp application, immediately after application of Axtriol-B Gel. Axtriol-B Gel should remain on the skin during the night or during the day.

When using the bottle

The bottle should be shaken before use and Axtriol-B Gel applied to the affected area. The hands should be washed after use.

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=====**OVERDOSE AND TREATMENT:** Use above the recommended dose may cause elevate serum calcium which subsides when treatment is discontinued. The symptoms of hypercalcemia include polyuria, constipation, muscle weakness, confusion and coma.

=====**Excessive prolonged use of topical corticosteroids may suppress the pituitary-adrenal functions, resulting in secondary adrenal insufficiency which is usually reversible. In such cases, symptomatic treatment is indicated.**

In case of chronic toxicity, the corticosteroid treatment must be discontinued gradually.

=====**EFFECTS ON ABILITY TO DRIVE AND USE MACHINE**

Axtriol-B Gel has no or negligible influence on the ability to drive and use machines.

PACKING: 15g & 30g in HDPE bottle.

=====**STORAGE:** Store below 30°C. Do not refrigerate. Keep container well closed. Keep the bottle in the outer carton in order to protect from light. Keep out of reach of children.

RECOMMENDED SHELF-LIFE:

Unopened: 24 months

After first opening: 3 months

MANUFACTURER:

HOE Pharmaceuticals Sdn. Bhd.

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