Wynzora® (calcipotriol and betamethasone dipropionate)
PRESCRIBING INFORMATION

Please consult the Summary of Product Characteristics (SmPC) before prescribing

Name: Wynzora, 50 micrograms/g + 0.5 mg/g cream

Active Ingredient: One gram of Wynzora Cream contains 50 micrograms of calcipotriol and betamethasone dipropionate equivalent to 0.5 mg betamethasone. *Excipients with known effect*: Butylated hydroxyanisole (E 320) 1.0 micrograms/g cream Macrogolglycerol hydroxystearate 3.4 micrograms/g cream

Indication: Wynzora is indicated for topical treatment of mild to moderate psoriasis vulgaris, including scalp psoriasis, in adults.

Dosage and Administration: Rub a thin layer of Wynzora Cream to affected areas once daily for up to 8 weeks. Discontinue when control is achieved. Treatment should be continued only after medical review and under regular medical supervision. For calcipotriol containing medicinal products, do not exceed the maximum daily dose of 15 g; the body surface area treated should not exceed 30%. Wynzora Cream should not be applied directly to the face or eyes. Allow 8 hours between the application and showering or bathing. Hands must be washed after use. *Consult SmPC and package leaflet for full method of administration.*

Contraindications, Precautions and Warnings:
Contraindications: Hypersensitivity to the active substances or to any of the excipients listed in section 6.1 of SmPC. Wynzora Cream is contraindicated in erythrodermic, exfoliative and pustular psoriasis; in patients with known disorders of calcium metabolism; 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.
Precautions: Avoid application under occlusive dressings, large areas of damaged skin or on mucous membranes or in skin folds due to increased corticosteroids systemic absorption and potential adrenocortical suppression or impact on the metabolic control of diabetes mellitus. Hypothalamic–pituitary–adrenal axis suppression was evaluated in adult subjects (N=27) with extensive psoriasis (including scalp). Adrenal suppression was seen in 1 out of 27 subjects (3.7%) after 4 weeks of treatment, and in one additional patient after 8 weeks of treatment. Visual disturbance may be reported with systemic and topical corticosteroid use. Patients presenting with blurred vision or other visual disturbances should be considered for a referral to an ophthalmologist. Hypercalcaemia may occur however the risk is minimal if maximum daily dose (15 g) is not exceeded. Serum calcium is normalised upon discontinuation. Avoid concurrent treatment with other steroids on the same treatment area. Do not use on the face and genital areas. Patients should wash hands after each application. Treat secondarily infected lesions with antimicrobiological therapy. Stop treatment with corticosteroids if the infection worsens. Continue medical supervision in the post-treatment period in case of rebound effects or development of generalised pustular psoriasis. Discontinue treatment in case of adverse reactions related to long-term use of corticosteroid. Limit or avoid excessive exposure to either natural or artificial sunlight during treatment. Consider risk/benefits balance of the use of topical calcipotriol with ultra-violet radiation. Butylhydroxyanisole (E320) contained in Wynzora Cream may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes. Macrogolglycerol hydroxystearate contained in Wynzora Cream may cause skin reactions. Do not smoke or go near naked flames due to the risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it. *Consult SmPC and package leaflet for more information.*

Fertility, pregnancy and lactation: *Fertility:* No impairment of male and female fertility (animal studies). *Pregnancy:* No adequate data available. The potential risk for humans is uncertain. Carefully consider benefit/risk balance during pregnancy. *Lactation:* Exercise caution in breast-feeding women. Do not use Wynzora Cream on the breast when breast-feeding. *Consult SmPC and package leaflet for more information.*

Adverse Reactions: All reported adverse reactions were seen at a frequency below 1%. *Uncommon:* Application site reactions including application site irritation, pain, pruritus, eczema, exfoliation, telangiectasia and folliculitis. Rash, urticaria and pruritus. Insomnia. *Not known (cannot be estimated from available data):*Vision, blurred. ***Adverse reactions considered to be related to the pharmacological classes of calcipotriol and betamethasone.*** *Calcipotriol*: 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. Very rarely cases of hypercalcaemia or hypercalciuria. *Betamethasone (as dipropionate)*: Skin atrophy, telangiectasia, striae, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, depigmentation and colloid milia. Generalised pustular psoriasis. Systemic reactions are rare in adults, but can be severe. Long-term treatment may cause adrenocortical suppression, cataract, infections, impact on the metabolic control of diabetes mellitus and increase of intraocular pressure. Systemic reaction may occur when applied under occlusion (plastic, skinfolds), on large areas and during long-term treatment. *Consult SmPC and package leaflet for further information.*

Legal Category: Ireland: POM
Subject to prescription which may not be renewed (A).
United Kingdom: POM
Price: Ireland: Price to wholesaler
United Kingdom: UK NHS Cost: £35.66 (excluding VAT).
Marketing Authorisation Numbers:
Ireland: PA 0968/006/001; **United Kingdom:** PL 16973/0044
Marketing Authorisation Holder:
Almirall, S.A., Ronda General Mitre, 151 08022 Barcelona, Spain
Further information available from:
Almirall Limited, Harman House, 1 George Street, Uxbridge, Middlesex, UB8 1QQ, UK.
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UK-Adverse events should be reported.
Reporting forms and information can be found at MHRA
https://yellowcard.mhra.gov.uk
Adverse events should be also reported to
Almirall Ltd. Tel. 0800 0087 399

IE-Adverse events should be reported.
Reporting forms and information can be found at HPRA
Pharmacovigilance, Website: www.hpra.ie.
Adverse events should be also reported to
Almirall Ltd. Tel. +353 (0) 1431 9836