

New Drug Bulletin: Calcitriol Ointment 3 mcg/g (Vectical® - Galderma)

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Calcitriol ointment 3 mcg/g (Vectical®) is a topical vitamin D₃ analogue labeled for treating mild to moderate plaque psoriasis. It was approved on January 23, 2009 for use in adults ages 18 and older. Its mechanism of action in treating plaque psoriasis is unknown, but may be associated with modulating keratinocyte proliferation and differentiation, key factors in psoriasis pathology.

Limited information is available on the pharmacokinetic parameters of calcitriol ointment. Application of 15 grams twice daily to 35% of the body surface area for 21 days increased mean plasma C_{max} values of calcitriol by approximately 36% over baseline and mean plasma AUC_(0-12hr) of calcitriol by 44%. No correlation was found between elevated calcitriol levels and albumin adjusted calcium, serum phosphorus, urinary calcium, or urinary phosphorus.

Two randomized, multicenter, double-blind, vehicle-controlled studies with a total of 839 subjects found that calcitriol ointment was more effective than a placebo vehicle for treating mild to moderate psoriasis. The subjects in the studies were treated twice daily over an 8-week period. Psoriasis was rated as clear or minimal more frequently with calcitriol ointment (21-23%) than with matching vehicle (7-14%).

Common adverse reactions included unspecified lab test abnormalities (8%), urine abnormalities (4%), psoriasis (4%), hypercalciuria (3%), and pruritus (3%). Controlled clinical trials of subjects who were treated twice daily for 8 weeks found hypercalcemia in 24% of subjects who underwent laboratory monitoring, but all serum calcium levels were less than 10% above the upper limit of normal. Product labeling recommends discontinuing treatment if hypercalcemia occurs, but calcium monitoring guidance is not addressed. Acute blistering dermatitis, erythema, pruritus, skin burning sensation, and skin discomfort have all been reported in world-wide post-marketing experience with calcitriol ointment. The incidence of these events is unknown.

Exercise caution in patients who are concomitantly receiving medications that may increase serum calcium level, such as thiazide diuretics, calcium supplements, or high doses of vitamin D. Calcitriol ointment may enhance the ability of ultraviolet radiation to induce skin tumors; avoid exposure to natural or artificial sunlight (including phototherapy).

Rub calcitriol ointment into psoriatic areas twice daily until fully absorbed. The maximum weekly dose should not exceed 200 grams because of the potential for systemic absorption. Do not apply to oral, facial, ophthalmic, or intravaginal areas.

Calcitriol ointment contains 3 mcg of calcitriol per gram of ointment and will be available in a 5 or 100 gram tube. Currently only the 100 gram tube is available. Store at room temperature (59° to 86°F), not refrigerated or frozen. The wholesale acquisition cost (WAC) of calcitriol ointment is presented in Table 1. Average wholesale price (AWP) is not yet available for this product.

Table 1: Cost of Vectical®

Package Size	WAC per Tube
5 gram tube	Unavailable
100 gram tube	\$15.45 per tube

Abbreviation: WAC = Wholesale acquisition cost

In summary, calcitriol ointment is a topical vitamin D₃ analogue applied twice daily for treating mild to moderate plaque psoriasis in adults. This presents another topical treatment option for patients with this condition.

References:

1. Vectical (calcitriol) package insert. Fort Worth, TX. Galderma Laboratories;2009.
2. Lamba S, Lebwohl M. Combination therapy with vitamin D analogues. *Br J Dermatol.* 2001;144(58 Suppl):27-32.

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