The intensity of UV radiation exposure may be tied to the prevalence of dermatomyositis in women, shown here.

VECTICAL® (calcitriol) OINTMENT, 3 mcg/g

For topical use only. Not for oral, intranasal, or intravaginal use. Not to be applied to the eyes, lips, or facial skin.

BRIEF SUMMARY

INDICATIONS AND USAGE:
VECTICAL Ointment is a vitamin D analog intended for the topical treatment of mild to moderate plaque psoriasis in adults 18 years and older.

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS

Effects on Calcium Metabolism
In controlled clinical trials with VECTICAL Ointment, among subjects having laboratory monitoring, hypercalcemia was observed in 24% (17/74) of subjects exposed to active drug and in 16% (13/79) of subjects exposed to vehicle. However, the increases in calcium and albumin-adjusted calcium levels were less than 1 mg/dL above the upper limit of normal. If aberrations in parameters of calcium metabolism occur, treatment should be discontinued until these parameters have normalized. The effects of VECTICAL Ointment on calcium metabolism following treatment durations greater than 52 weeks have not been evaluated. Increased absorption may occur with occlusive use.

Ultrasound Light Exposure
Animal data suggest that the vehicle of VECTICAL Ointment may enhance the ability of ultraviolet radiation (UVR) to induce skin tumors.

Subjects who apply VECTICAL Ointment to exposed skin should avoid excessive exposure of the treated areas to either natural or artificial sunlight, including tanning booths and sunlamps. Physicians may wish to limit or avoid use of phototherapy in patients who use VECTICAL Ointment.

Undesired Use

The safety and effectiveness of VECTICAL Ointment in patients with known or suspected disorders of calcium metabolism have not been evaluated. The safety and effectiveness of VECTICAL Ointment in patients with erythrodermic, exfoliative, or pustular psoriasis have not been evaluated.

ADVERSE REACTIONS

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

Clinical Studies Experience

VECTICAL Ointment was studied in two vehicle-controlled studies (419 subjects), and in one open label study (324 subjects). The table below describes exposure to VECTICAL Ointment in 724 subjects, including 239 exposed for 6 months and 116 exposed for one year.

Furthermore, 301 subjects were treated with VECTICAL Ointment twice daily for 8 weeks. The population included subjects aged 13 to 87, males (284) and females (274), and Caucasians (47); with mild to moderate (313) chronic plaque psoriasis.

Selected Adverse Events in at Least 1% of Subjects in the Two Pooled Vehicle-Controlled Studies

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>VECTICAL Ointment</th>
<th>Placebo Ointment</th>
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<tbody>
<tr>
<td>Discomfort skin</td>
<td>3%</td>
<td>2%</td>
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<td>Pruritus</td>
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Among subjects having laboratory monitoring, hypercalcemia was observed in 24% (17/74) of subjects exposed to active drug and in 16% (13/79) of subjects exposed to vehicle. However, the elevations were less than 10% above the upper limit of normal. The open label study enrolled 324 subjects with psoriasis who were then treated for up to 52 weeks. Adverse events reported at a rate of greater than or equal to 2% of subjects treated with VECTICAL Ointment were lab test abnormality (5%), urine abnormality (4%), pruritus (4%), hypercalciuria (3%), and pruritus (3%).

Kidney stones were reported in 3 subjects and confirmed in two.

Prolonged UV Exposure

The following adverse reactions have been identified during worldwide post-approval experience with VECTICAL Ointment: acute blistersing dermatitis, erythema, pruritus, skin burning sensation, and skin discomfort. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

DRUG INTERACTIONS

VECTICAL Ointment should be used with caution in patients receiving medications known to increase the serum calcium level, such as thiazide diuretics. Caution should also be exercised in patients receiving calcium supplements or high doses of vitamin D.

INFORMATION FOR PATIENTS

The information in this leaflet is intended to be safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects. Patients using VECTICAL Ointment should receive the following information:

Instructions for Use
This medication is to be used as directed by the physician. It is for external use only. This medication is to be applied only to areas of the skin affected by psoriasis, as directed. It should be gently rubbed into the skin so that no medication remains visible.

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