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February 5, 2009 — The US Food and Drug Administration (FDA) recently approved calcitriol ointment 3 µg/g (*Vectical*, Galderma Laboratories, LP), a first-of-its-kind, topical ointment, using a naturally occurring active form of vitamin D₃ to treat psoriasis.

For treatment of mild-to-moderate psoriasis plaque in adults aged 18 years and older, calcitriol ointment has been proven safe, even for use in sensitive skin areas, and well-tolerated for continuous use up to 1 year. Calcitriol ointment, which is believed to help regulate excessive skin cell production by binding to the vitamin D receptors on keratinocytes (skin cells), is the only vitamin D₃ ointment of its kind available in the United States.

"Because psoriasis is a chronic disease, topical products that are safe for extended use must fit within overall, long-term treatment regimens," Mark Lebwohl, MD, from Mount Sinai School of Medicine in New York City, said in a news release. "The [ointment]...has been proven safe and well-tolerated throughout 52 weeks of continuous use in treating mild-to-moderate disease. A safe, effective long-term therapy is critical to improve overall outcomes for these patients."

FDA approval was based on findings from two 8-week studies of more than 800 patients comparing twice-daily doses of calcitriol ointment with vehicle. Improvements in mild-to-moderate plaque psoriasis severity in the first study were first apparent at week 2, and these benefits were sustained during the 8-week treatment period.

Treatment success, defined as a global severity score of clear/minimal, was achieved by study end in 34% of patients treated with calcitriol ointment vs 22% of those treated with vehicle. At 8 weeks, 23% of patients achieved treatment success and also had a 2-grade improvement in disease severity. Efficacy results were similar in the second study.

The calcitriol ointment and vehicle groups had similar treatment-related adverse events. The most common adverse events (reported in more than 3%) were laboratory test abnormality, urine abnormality, psoriasis, hypercalciuria, pruritus, and skin discomfort.

A long-term, 52-week safety study showed that adverse events were similar to those reported in the 8-week studies. Although the 8-week studies showed some transient increases in plasma calcium levels, calcitriol ointment was not associated with any significant clinical effects on calcium homeostasis when used continuously during the 52-week study.

Psoriasis, a chronic skin disorder affecting 2% to 3% of the US population (about 7.5 million people) is characterized by thick, red, dry, scaly patches of skin and is caused by an abnormally high growth rate of skin cells that form plaques. Physical symptoms include inflammation, infection, soreness, and burning.

Patients with psoriasis may also have diabetes, heart disease, and obesity. Other available prescription options for psoriasis include corticosteroids, which are not typically used long term.