For the use only of Registered Medical Practitioner or a Hospital or a Laboratory.

TRIOL®

Calcitriol 3 mcg

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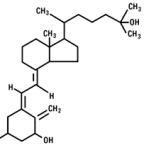
DESCRIPTION

Calcitriol Ointment 3 mcg/g is a vitamin D analog intended for topical application to the skin. The chemical name of the active ingredient is (5Z,7E)-9,10-secocholesta-5,7,10(19)-triene-1α,3β,25-triol. The structural formula is:



Calcitriol is a white or almost white crystalline solid. It is practically insoluble in water, soluble in alcohol and in fatty oils. The molecular formula is C27H44O3, and the molecular weight is 416.64. Calcitriol Ointment is a translucent ointment containing 3 mcg/g (0.0003% w/w) of calcitriol, packaged in laminated tubes with screw caps.

INDICATIONS AND USAGE:

Calcitriol Ointment is indicated for the topical treatment of mild to moderate plaque psoriasis in adults 18 years and older.

Limitations of Use: Calcitriol Ointment should not be applied to the eyes, lips, or facial skin.

DOSAGE AND ADMINISTRATION:

Apply Calcitriol Ointment to affected areas twice daily, morning and evening. The maximum weekly dose should not exceed 200 grams. Calcitriol Ointment is not for oral, ophthalmic or intravaginal use.

CONTRAINDICATIONS:

None.

MECHANISM OF ACTION:

The mechanism of action of calcitriol in the treatment of psoriasis has not been established.

USE IN SPECIFIC POPULATIONS:

Usage in Pregnancy:

Pregnancy Category C

Nursing Mothers:

It is not known whether calcitriol is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Calcitriol Ointment is administered to a nursing woman.

Pediatric Use:

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use:

Clinical studies of Calcitriol Ointment did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported experience has not identified differences in responses between the elderly and younger patients.

WARNINGS AND PRECAUTIONS:

Effects on Calcium Metabolism:

In controlled clinical trials with Calcitriol Ointment, among subjects having laboratory monitoring, hypercalcemia was observed in 24% (18/74) 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 10% 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 Calcitriol Ointment on calcium metabolism following treatment durations greater than 52 weeks have not been evaluated. Increased absorption may occur with occlusive use.

Ultraviolet Light Exposure:

Animal data suggest that the vehicle of Calcitriol Ointment may enhance the ability of ultraviolet radiation (UVR) to induce skin tumors [see Carcinogenesis, Mutagenesis, Impairment of Fertility].

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

Unevaluated Uses:

The safety and effectiveness of Calcitriol Ointment in patients with known or suspected disorders of calcium metabolism have not been evaluated.

The safety and effectiveness of Calcitriol Ointment in patients with erythrodermic, exfoliative, or pustular psoriasis have not been evaluated.

ADVERSE REACTIONS:

Acute blistering dermatitis, erythema, pruritus, skin burning sensation, and skin discomfort.

OVERDOSAGE:

Topically applied calcitriol can be absorbed in sufficient amounts to produce systemic effects [see WARNINGS AND PRECAUTIONS].

DRUG INTERACTIONS:

Calcitriol 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 [see WARNINGS AND PRECAUTIONS].

PHARMACOKINETICS:

The systemic exposure of calcitriol was assessed in subjects with chronic, plaque psoriasis. In the pivotal pharmacokinetic/pharmacodynamic study, calcitriol ointment 3 mcg/g, was applied twice daily for 21 days (for a total dose of 30 g/day) to 35% of the body surface area (psoriatic + surrounding healthy skin) of subjects with at least 25% of body surface area involvement. At Day 21, the geometric mean plasma concentration values of Cmax increased by approximately 36% over baseline and the geometric mean value of AUC0-12 hr increased by 44%. There was no correlation between the elevated calcitriol levels and the pharmacodynamic parameters of serum albumin adjusted calcium, serum phosphorus, urinary calcium and urinary phosphorus.

STORAGE:

Store at 25°C (77°F); excursions permitted to 15° - 30° C (59° - 86° F) [See USP Controlled Room Temperature.] Do not freeze or refrigerate.

Manufactured by:

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