



### COMPOSITION:

Each gram of ointment contains: Calcipotriol (as hydrate) BP ... 50mcg. [BP Specs.]

# PHARMACOLOGICAL PROPERTIES:

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Calcipotriol Ointment is a topical formulation of the Vitamin-D derivative, Calcipotriol, which induces differentiation and suppresses proliferation of skin cells (keratinocytes). Calcipotriol Ointment thus normalizes abnormal cell proliferation and differentiation of psoriatic skin. Calcipotriol Ointment is only slightly absorbed from the skin.

### INDICATION:

Dervit (Calcipotriol) Ointment is indicated for the topical treatment of plaque psoriasis (psoriasis vulgaris) amenable to topical therapy.

### CONTRA-INDICATIONS:

Hypersensitivity to the active substance or any of the excipients of product. Patients with known disorder of calcium metabolism and patients with severe liver and kidney disease.

### DOSAGE AND ADMINISTRATION:

Adults:

Dervit Ointment should be applied to the affected area twice daily. Maximum weekly dose should not exceed 100g. Children over 12 years:

Dervit Ointment should be applied to the affected area twice daily. Maximum weekly dose should not exceed 75g.

Children aged 6 to 12 years:

Dervit Ointment should be applied to the affected area twice daily. Maximum weekly dose should not exceed 50g.

Children under 6 years:
There is limited experience of the use of **Dervit** Ointment in this age group. A maximum safe dose has not been

established. These dose recommendations are based on extensive experience in adults. In respect of children, clinical experience in children has shown **Dervit** Ointment to be safe and effective over eight weeks at a mean dose of 15g per week but with wide variability in dose among patients. Individual dose requirement depends on the extent of psoriasis but should not exceed the above recommendations. There is no experience of use of **Dervit** Ointment in combination with other therapies in children.

Usage of the above recommended dose may cause elevated serum calcium which quickly subsides when treatment is discontinued. Hypercalcaemia has been reported at lower doses in patients with generalised pustular or erythrodermic exfoliative psoriasis. The clinical signs of hypercalcaemia include anorexia, nausea, vomiting, constipation, hypotonia, depression, lethargy and coma.

SIDE EFFECTS:
Minor adverse effects such as transient local irritation and very rarely, facial dermatitis may occur. The most frequently adverse reactions during treatment are pruritus, skin irritation and erythema.

### **WARNING & PRECAUTIONS:**

Calcipotriol Ointment should not be used on the face. Patients should be advised to wash their hands after applying the ointment and to avoid inadvertent transfer to other body areas, especially the face.

During treatment with Calcipotriol Ointment physicians are recommended to advise patients to limit or avoid excessive

exposure to either natural or artificial sunlight.

## USE IN PREGNANCY:

The safety of the use of Calcipotriol during human pregnancy has not been established and studies in animals have shown reproductive toxicity when Calcipotriol was administered orally. Calcipotriol should not be used during pregnancy unless clearly necessary.

### **USE IN LACTATION:**

It is not known whether Calcipotriol is excreted in breast milk. A decision on whether to abstain from breast-feeding or to abstain from therapy with Calcipotriol Ointment should be made taking into account the benefit of breast-feeding to the newborn/infant and the benefit of Calcipotriol Ointment therapy to the woman.

### INSTRUCTIONS:

For external use only.

Store below 30°C. Protect from heat and light. Keep out of the reach of children.

**PRESENTATION: Dervit** Ointment (Calcipotriol) is available in pack size of 30g.

Manufactured by: NABIQASIM INDUSTRIES (PVT) LTD. 17/24, Korangi Industrial Area,

PHARMA Karachi-Pakistan.

مدایات: ۳۰ ڈگری پینٹی گریڈے کم درجہ ترارت پر رکھیں۔ گری اور روثن سے بچائیں۔ بچول کی پہنٹے سے دور رکھیں۔