

Calcipotriol 0.005%

COMPOSITION

Dyvon[™] Cream: Each gm cream contains Calcipotriol Monohydrate BP 0.052 mg equivalent to 0.05 mg Calcipotriol BP.

Dyvon[™] Ointment: Each gm ointment contains Calcipotriol Monohydrate BP 0.052 mg equivalent to 0.05 mg Calcipotriol BP.

PHARMACOLOGY

Calcipotriol is a non-steroidal antipsoriatic agent, derived from vitamin D. Calcipotriol exhibits a vitamin D-like effect by competing for the 1,25(OH)2D3 receptor. Calcipotriol is as potent as 1,25(OH)2D3, the naturally occurring active form of vitamin D, in regulating cell proliferation and cell differentiation, but much less active than 1,25(OH)2D3 in its effect on calcium metabolism. Calcipotriol induces differentiation and suppresses proliferation (without any evidence of a cytotoxic effect) of keratinocytes, thus reversing the abnormal keratinocyte changes in psoriasis. The therapeutic goal envisaged with calcipotriol is thus a normalization of epidermal growth.

INDICATION

Dyvon[™] cream & ointment is indicated for the topical treatment of chronic stable plaque type psoriasis vulgaris in adult patients.

DOSAGE AND ADMINISTRATION

Adults:

Dyvon[™] cream & ointment should be applied topically to the affected area twice daily (i.e. in the morning and in the evening). Less frequent application may be indicated after the initial period of treatment. After satisfactory improvement has occurred, treatment should be discontinued. If recurrence takes place after discontinuation, the treatment may be reinstituted. Experience is lacking in the use of calcipotriol for periods longer than 1 year. The maximum recommended weekly dose of calcipotriol cream is 100gm/week. Children:

Dyvon[™] cream & ointment should not be used in children, as there is inadequate experience with its use.

CONTRAINDICATION

Calcipotriol cream & ointment is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations. It is also contraindicated in patients with known disorders of calcium metabolism.

PRECAUTION

Calcipotriol cream & ointment is not recommended for use in patients with generalized pustular psoriasis, guttate psoriasis and erythrodermic exfoliate psoriasis.

Calcipotriol cream & ointment is not recommended for use on the face. USE IN PREGNANCY & LACTATION

Pregnancy

Safety for use in pregnancy has not been established. Therefore calcipotriol should not be used during pregnancy unless benefits clearly outweigh the risks. Lactation

It is not known whether calcipotriol is excreted in breast milk, therefore, the drug should be used during lactation only if the benefits clearly outweigh the risks.

Calcipotriol should not be applied to the chest area during breast feeding to avoid possible ingestion by infants.

ADVERSE REACTION

Photosensitivity reactions, skin discolouration, bullous eruption, skin exfoliation, contact dermatitis and allergic reactions have been reported with topical calcipotriol therapy.

STORAGE

Store below 25° C, away from light and moisture. Do not freeze. Keep all medicines out of reach of children.

HOW SUPPLIED

Dyvon[™] Cream - Each pack has a laminated tube containing 20 gm cream.

Dyvon[™] Ointment - Each pack has a laminated tube containing 20 gm ointment.





Revision No.:00