Dyvon™ Plus

Betamethasone 0.05% + Calcipotriol 0.005%

Composition
Dyvon™ Plus Ointment: Each gm ointment contains Betamethasone 0.5 mg as Betamethasone Dipropionate BP and Calcipotriol BP 0.05 mg.
Dyvon™ Plus Topical Suspension: Each gm topical suspension contains Betamethasone 0.5 mg as Betamethasone Dipropionate BP and Calcipotriol 0.05 mg as Calcipotriol Monohydrate BP.

Pharmacology
Betamethasone Dipropionate is a potent topically-active corticosteroid producing prompt, marked and prolonged anti-inflammatory, antipruritic, vasoconstrictive and immunosuppressive properties, without curing the underlying condition. These effects can be enhanced under occlusive conditions due to increased penetration of stratum corneum (by approximately a factor of 10).
Calcipotriol is a non-steroidal antipsoriatic agent, derived from vitamin D. Calcipotriol exhibits a vitamin D-like effect by competing for the 1, 25$(OH)_2D_3$ receptor. Calcipotriol is as potent as 1,25$(OH)_2D_3$, the naturally occurring active form of vitamin D, in regulating cell proliferation and cell differentiation, but much less active than 1,25$(OH)_2D_3$ 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™ Plus Ointment is indicated for the topical treatment of plaque-type psoriasis vulgaris amenable to topical therapy.
Dyvon™ Plus Topical Suspension is indicated for the topical treatment of plaque psoriasis of the scalp and body.

Dosage and administration
Dyvon™ Plus Ointment: **Dyvon™ Plus** Ointment is indicated for topical use only. The phototoxic effects of **Dyvon™ Plus** Ointment have not been studied in psoriasis patients. All psoriasis-affected areas treated with **Dyvon™ Plus** Ointment should be, where possible, protected from direct sunlight and UV-light with items of clothing.
Adults: **Dyvon™ Plus** Ointment should be applied topically to the affected area once daily. The maximum daily dose should not exceed 15 gm.
The maximum recommended weekly dose of **Dyvon™ Plus** Ointment is 100 gm/week. The treated area should not be more than 30% of the body surface.
The use of **Dyvon™ Plus** Ointment should be intermittent for up to one year under close medical supervision. Treatment should be limited to four week periods with Calcipotriol used alone for one month between periods of use of **Dyvon™ Plus** Ointment as needed.
Children: **Dyvon™ Plus** Ointment is not recommended for use in children and adolescents below the age of 18 years.

Dyvon™ Plus Topical Suspension: Apply required quantity of spray of Topical Suspension once daily to the affected areas and gently rub in using the tips of the fingers. Treatment may be continued for up to 8 weeks. Treatment may be discontinued earlier, if symptoms are cleared. The maximum weekly dose should not exceed 100 gm. Shake before use. **Dyvon™ Plus** Topical Suspension is not for oral, ophthalmic or intravaginal use.

Contraindication
Betamethasone and Calcipotriol containing preparation is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation. It is also contraindicated in patients with known disorders of calcium metabolism. Patients with severe renal insufficiency or severe hepatic disorders are also contraindicated.

Precaution
Hypercalcemia and hypercalciuria have been reported. If either occurs, discontinue until parameters of calcium metabolism normalize. Topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome and unmask latent diabetes. Rate of adrenal suppression increased with treatment duration. Systemic absorption may require evaluation for HPA axis suppression. Modify use if HPA axis suppression develops. Potent corticosteroids, use on large areas, prolonged use or occlusive use may increase systemic absorption. Local adverse reactions may include atrophy, striae, irritation, acne form eruptions, hypopigmentation, and allergic contact dermatitis and may be more likely with occlusive use or more potent corticosteroids. Use is not recommended on face, axillae, groin or where atrophy is present. Children may be more susceptible to systemic toxicity when treated with topical corticosteroids.

Adverse reactions
The most common adverse reactions are folliculitis and burning sensation of skin.

Use in pregnancy and lactation
There are no adequate and well-controlled studies in pregnant women. Ointment or suspension should be used during pregnancy only if the potential benefit to the patient justifies the potential risk to the fetus.
Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topically administered calcipotriene or corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk.
Because many drugs are excreted in human milk, caution should be exercised when Calcipotriol and Betamethasone ointment or suspension is administered to a nursing woman.

Storage
Store in a cool (below 25°C) & dry place & protect from light. Do not refrigerate. Keep out of the reach of children.

How supplied
Dyvon™ Plus Ointment: Each pack has a laminated tube containing 20 gm ointment.
Dyvon™ Plus Topical Suspension: Each pack has an HDPE container containing 25 ml topical suspension.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
Pabna, Bangladesh

TM-Trade Mark

Revision No.: 01