DERMOVATE™ Clobetasol propionate. COMPOSITION: DERMOVATE Cream and Ointment contains clobetasol propionate 0.05 % w/w. Indications: DERMOVATE is a very potent topical corticosteroid indicated for adults, elderly and children over 1 year for the relief of the inflammatory and pruritic manifestations of steroid responsive dermatoses. These conditions include the following: Psoriasis (excluding widespread plaque psoriasis), Recalcitrant dermatoses, Lichen planus,Discoid lupus erythematosus, Other skin conditions which do not respond satisfactorily to less potent steroids. Dosage and Administration: Ointment: Ointments are especially appropriate for dry, lichenified or scarred lesions. Cream: Creams are especially appropriate for thin, moist, or weeping surfaces. Adults, Elderly and Children over 1 year. Apply thinly and gently rub in using only enough to cover the entire affected area once or twice a day for up to 4 weeks until improvement occurs, then reduce the frequency of application or change the treatment to a less potent preparation. Allow adequate time for absorption after each application before applying an emollient. Repeated short courses of DERMOVATE may be used for relatively resistant lesions, especially where these have a tendency to recur. In more resistant dermatomic effects of DERMOVATE can be enhanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response. Thereafter improvement can usually be maintained by application without occlusion. If the condition worsens or does not improve within 2-4 weeks, treatment and diagnosis should be re-evaluated. Treatment should not be continued for more than 4 weeks. If continuous treatment is necessary, a less potent preparation should be used. The maximum weekly dose should not exceed 50gms/week. Atopic dermatitis (eczema): Therapy with DERMOVATE cream and ointment should be gradually discontinued once control is achieved and an emollient continued as maintenance therapy. Rebound of pre-existing disease may be anticipated should PADERMOVATE. Recalcitrant dermatoses may be controlled by the administration of appropriate antimicrobial therapy. If an acute episode has been treated effectively with a continuous course of topical corticosteroid, intermittent dosing (once daily, twice weekly, without occlusion) may be considered. This has been shown to be helpful in reducing the frequency of relapse. Application at night is recommended in children due to the smaller total area of skin exposed. Children: DERMOVATE is contraindicated in children under one year of age. Children are more likely to develop local and systemic side effects of topical corticosteroids and, in general, require shorter courses and less potent agents than the adults. Care should be taken when using DERMOVATE to ensure the amount applied is the minimum that provides therapeutic benefit. Elderly: Clinical studies have not identified differences in responses between the elderly and younger patients. The greater frequency of decreased hepatic or renal function in the elderly may delay elimination if systemic absorption occurs. Therefore the minimum quantity should be used and the shortest duration should be employed. Renal / Hepatic Impairment: Hypersensitivity: When application is over a large surface area for a prolonged period) metabolism and elimination may be delayed therefore increasing the risk of systemic toxicity. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit. Local infectious conditions should not be treated with DERMOVATE. Cutaneous infections, Rosacea, Acne vulgaris, Puritus without inflammation, Perianal and genital pruritus, Perioral dermatitis. DERMOVATE is contraindicated in dermatoises in children less than one year of age, including dermatitis. Warnings and Precautions: DERMOVATE should be used with caution in patients with a history of local hypersensitivity to corticosteroids or to any of the excipients in the preparation. Local symptoms or systemic symptoms may resemble manifestations of systemic hypercortisolism (Cushing’s syndrome) and reversible hypothalamic-pituitary-adenal (HPA) axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals as a result of increased systemic absorption of topical steroids. If either of the above are observed, withdrawal or alteration of the drug gradually by substituting a less potent corticosteroid. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency. Risk factors for increased systemic effects are: Potency and formulation of topical steroid, Duration of exposure. Application to a large surface area, Use on occluded areas. Infections: In the event of infection is encouraged by the warm, moist conditions within skin folds or caused by occlusive dressings. When using occlusive dressings, the skin should be cleansed before a fresh dressing is applied. Use in psoriasis: Topical corticosteroids should be used with caution in psoriasis as rebound relapses, development of tolerances, risk of generalised purulater psoriasis and development of atrophy. The skin should be cleansed before a fresh dressing is applied. Use in skin disorders which have been reported in some cases. If used or suspected in pregnant women the barrier function of the skin is not permanent and therefore dermatitis around chronic lesions may develop. In contrast with chronic chronic lesions which heal with time. However, use of this may be associated with a higher occurrence of local hypersensitivity reactions and an increased risk of local infection. Application to the face: Application to the face is undesirable as this area is more susceptible to atrophic changes. If used on the face, treatment should be limited to only a few days and reviewed weekly. Infection with occlusion: Bacterial infection is encouraged by the warm, moist conditions within skin folds or caused by occlusive dressings. When using occlusive dressings, the skin should be cleansed before a fresh dressing is applied. Use in psoriasis: Topical corticosteroids should be used with caution in psoriasis as rebound relapses, development of tolerances, risk of generalised purulater psoriasis and development of atrophy. The skin should be cleansed before a fresh dressing is applied. Use in skin disorders which have been reported in some cases. If used or suspected in pregnant women the barrier function of the skin is not permanent and therefore dermatitis around chronic lesions may develop. In contrast with chronic chronic lesions which heal with time. However, use of this may be associated with a higher occurrence of local hypersensitivity reactions and an increased risk of local infection. Application to the face: Application to the face is undesirable as this area is more susceptible to atrophic changes. If used on the face, treatment should be limited to only a few days and reviewed weekly. Infection with occlusion: Bacterial infection is encouraged by the warm, moist conditions within skin folds or caused by occlusive dressings. When using occlusive dressings, the skin should be cleansed before a fresh dressing is applied. There are limited data from the use of DERMOVATE in pregnant women. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to humans has not been established. Administration of DERMOVATE during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the foetus. The minimum quantity should be used for the minimum duration. Lactation: The safe use of topical corticosteroids during lactation has not been established. It is advisable that the topical administration of corticosteroids could result in systemic absorption and pregnancy should be avoided where possible. Adrenal suppression: Adrenal suppression is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may occur. Treatment: In the event of overdose, DERMOVATE should be withdrawn gradually by reducing the frequency of
application or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency. Further management should be as clinically indicated or as recommended by the national poisons centre, where available. **Storage:** Store below 30°C.