EUMOVATE™ Clobetasone butyrate. Composition: **EUMOVATE** cream and ointment contains 0.05 % w/w clobetasone 17-butyrate. Cream and Ointment. **Indications:** **EUMOVATE** cream and ointment are moderately potent topical corticosteroids indicated for adults, elderly, children and infants for the relief of the inflammatory and pruritic manifestations of steroid responsive dermatoses. These include the following: Atopic dermatitis, Irritant or allergic contact dermatitis, Seborrhoeic dermatitis, Nappy rash, Photodermatitis, Otitis externa, Prurigo nodularis, Insect bite reactions. **EUMOVATE** may be used as maintenance therapy between courses of one of the more potent topical steroids. **Dosage and Administration:** Adults, Elderly, Children and Infants: Cream: Creams are especially appropriate for moist or weeping surfaces. Ointment: Ointments are especially appropriate for dry, lichenified or scaly lesions. Atopic dermatitis (eczema). Apply thinly and gently rub in using only enough to cover the entire affected area once or twice a day 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. If the condition worsens or does not improve within four weeks, treatment and diagnosis should be re-evaluated. Therapy with topical corticosteroids should be gradually discontinued once control is achieved and an emollient continued as maintenance therapy. Rebound of pre-existing dermatoses can occur with abrupt discontinuation of topical corticosteroids especially with potent preparations. Children: Children are more likely to develop local and systemic adverse reactions of topical corticosteroids and, in general, require shorter courses and less potent agents than adults. Care should be taken when using **EUMOVATE** 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 for the shortest duration to achieve the desired clinical benefit. Renal/Hepatic Impairment: In case of systemic absorption (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. **Contraindications:** The following conditions should not be treated with **EUMOVATE:** Untreated cutaneous infections, Rosacea, Acne vulgaris, Pruritus without inflammation. **Warnings and Precautions:** **EUMOVATE** 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 hypersensitivity reactions may resemble symptoms of the condition under treatment. Manifestations of hypercortisolism (Cushing’s syndrome) and reversible hypothalamic-pituitary-adrenal (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, withdraw the drug gradually by reducing the frequency of application or 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 of skin e.g. on intertriginous areas or under occlusive dressings (in infants the nappy may act as an occlusive dressing). Increasing hydration of the stratum corneum, Use on thin skin areas such as the face, Use on broken skin or other conditions where the skin barrier may be impaired, In comparison with adults, children and infants may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic adverse effects. This is because children have an immature skin barrier and a greater surface area to body weight ratio compared with adults. Children: In infants and children under 12 years of age, long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression is more likely to occur. Infection risk 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. Application to the face: Prolonged application to the face is undesirable as this area is more susceptible to atrophic changes. Application to the eyelids: If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as cataract and glaucoma might result from repeated exposure. Concomitant infection: Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and administration of appropriate antimicrobial therapy. Chronic leg ulcers: Topical corticosteroids are sometimes used to treat the dermatitis around chronic leg ulcers. However, this use may be associated with a higher occurrence of local hypersensitivity reactions and an increased risk of local infection. Accidental ingestion: For external use only. This and all medication should be kept out of the reach of children. In case of accidental ingestion, professional assistance should be sought or a national poison control centre contacted immediately. Interactions: Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant, depends on the dose and route of administration of the corticosteroids, and the potency of the CYP3A4 inhibitor. Pregnancy and Lactation: There are limited data from the use of EUMOVATE 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 EUMOVATE 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. The safe use of topical corticosteroids during lactation has not been established. It is not known whether the topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Administration of EUMOVATE during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant. If used during lactation, EUMOVATE should not be applied to the breasts to avoid accidental ingestion by the infant. There are no data in humans to evaluate the effect of topical corticosteroids on fertility. Effects on Ability to Drive and Use Machines: There have been no studies to investigate the effect of EUMOVATE on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical EUMOVATE. Adverse Reactions: Post-marketing data: Infections and Infestations: Very
rare: Opportunistic infection. Immune System Disorders: Very rare: Hypersensitivity. Endocrine Disorders: Very rare: Hypothalamic-pituitary adrenal (HPA) axis suppression: Cushingoid features (e.g. moon face, central obesity), delayed weight gain/growth retardation in children, osteoporosis, glaucoma, hyperglycaemia / glucosuria, cataract, hypertension, increased weight/obesity, and decreased endogenous cortisol levels. Skin and Subcutaneous Tissue Disorders: Very rare: Allergic contact dermatitis, urticaria, skin atrophy, pigmentation changes, exacerbation of underlying symptoms, local skin burning, hypertrichosis, rash, pruritus, erythema. **Overdose:** Topically applied EUMOVATE may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may occur. In the event of overdose, EUMOVATE 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. **Special Precautions for Storage:** Store cream and ointment at temperature not exceeding 30°C.