MALAYSIA Protopic® ointment 0.03% Abbreviated Product Information

COMPOSITION: 1 g of Protopic® 0.03% ointment contains 0.3 mg of tacrolimus as tacrolimus monohydrate (0.03%). THERAPEUTIC INDICATIONS: Protopic® 0.03% ointment is indicated for treatment of moderate to severe atopic dermatitis in adults, adolescents and children from the age of 2 years who are not adequately responsive to or are intolerant of conventional therapies such as topical corticosteroids. POSOLOGY AND METHOD OF ADMINISTRATION: Protopic® 0.03% ointment should be started twice a day for up to three weeks on children aged 2 years and above at the first appearance of signs and symptoms as a thin layer to affected or commonly affected areas of the skin including face, neck and flexure areas, except on mucous membranes, followed by once a day dosing until lesions are cleared, almost cleared or mildly affected. Protopic® ointment should not be applied under occlusion. Protopic® can be used for short-term and intermittent long-term treatment. At the first signs of recurrence (flares) of the disease symptoms, treatment should be re-initiated. For adult and adolescents aged 16 years and above, an attempt should be made to use Protopic® 0.03% ointment if the clinical condition allows. Generally, improvement is seen within one week of starting treatment. If no signs of improvement are seen after two weeks of treatment, further treatment options should be considered. CONTRAINDICATIONS: Hypersensitivity to the active substance, macrolides in general, or to any of the excipients. SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Physicians should advise patients on appropriate sun protection methods, such as minimisation of the time in the sun, use of a sunscreen product and covering of the skin with appropriate clothing. Protopic® ointment should not be applied to lesions that are considered to be potentially malignant or pre-malignant.The effect of treatment with Protopic® ointment on the developing immune system of children aged below 2 years has not been established. UNDESIRABLE EFFECTS: Application site burning and application site pruritus are very common adverse events of topically applied Protopic® ointment 0.03%. Local skin infections, alcohol intolerance, paraesthesia, dysaesthesia, pruritus, and application site warmth/erythema/pain/irritation/ paraesthesia/rash are common adverse events of topically applied Protopic® ointment 0.03%. Cases of malignancies, including cutaneous (i.e. cutaneous T Cell lymphomas) and other types of lymphoma, and skin cancers, have been reported in patients using tacrolimus ointment. SHELF LIFE: 24 months. SPECIAL PRECAUTIONS FOR STORAGE: Store at 30°C or below. Protopic® ointment 0.03% API version JAN2021.

MALAYSIA Protopic® 0.1% ointment Abbreviated Product Information

COMPOSITION: 1 g of Protopic® 0.1% ointment contains 1.0 mg of tacrolimus as tacrolimus monohydrate (0.1%). THERAPEUTIC INDICATIONS: Protopic® 0.1% ointment is indicated for treatment of moderate to severe atopic dermatitis in adults and adolescents (16 years of age and above) who are not adequately responsive to or are intolerant of conventional therapies such as topical corticosteroids. POSOLOGY AND METHOD OF ADMINISTRATION: Protopic® 0.1% ointment should be applied twice a day at the first appearance of signs and symptoms as a thin layer to affected or commonly affected areas of the skin including face, neck and flexure areas, except on mucous membranes, until lesions are cleared, almost cleared or mildly affected. Protopic® ointment should not be applied under occlusion. Protopic® can be used for short-term and intermittent long-term treatment. At the first signs of recurrence (flares) of the disease symptoms, treatment should be re-initiated. If symptoms recur, twice daily treatment with Protopic® 0.1% should be restarted. An attempt should be made to reduce the frequency of application or to use Protopic® 0.03% ointment if the clinical condition allows. Generally, improvement is seen within one week of starting treatment. CONTRAINDICATIONS: Hypersensitivity to the active substance, macrolides in general, or to any of the excipients. SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Physicians should advise patients on appropriate sun protection methods, such as minimisation of the time in the sun, use of a sunscreen product and covering of the skin with appropriate clothing. Protopic® ointment should not be applied to lesions that are considered to be potentially malignant or pre-malignant.The effect of treatment with PROTOPIC® ointment on the developing immune system of children aged below 2 years has not been established. UNDESIRABLE EFFECTS: Application site burning and application site pruritus are very common adverse events of topically applied Protopic® 0.1% ointment. Local skin infections, alcohol intolerance, paraesthesia, dysaesthesia, pruritus, and application site warmth/erythema/pain/irritation/paraesthesia/rash are common adverse events of topically applied Protopic® ointment 0.1%. Cases of malignancies, including cutaneous (i.e. cutaneous T Cell lymphomas) and other types of lymphoma, and skin cancers, have been reported in patients using tacrolimus ointment. SHELF LIFE: 24 months. STORAGE CONDITIONS: Store at 30°C or below. Protopic® 0.1% ointment API version JAN2021.