FLUDROXYCORTIDE TAPE
PRESCRIBING INFORMATION

Fludroxycortide 4 micrograms per square centimetre Tape
See full Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Transparent, plastic surgical tape impregnated with 4 micrograms fludroxycortide per square centimetre.

Indications: Adjunctive therapy for chronic, localised, recalcitrant dermatoses that may respond to topical corticosteroids and particularly dry, scaling lesions.

Posology and Method of Administration: *Adults and the Elderly*: For application to the skin, which should be clean, dry, and shorn of hair. In most instances the tape need only remain in place for 12 out of 24 hours. The tape is cut so as to cover the lesion and a quarter inch margin of normal skin. Corners should be rounded off. After removing the lining paper, the tape is applied to the centre of the lesion with gentle pressure and worked to the edges, avoiding excessive tension of the skin. If longer strips of tape are to be applied, the lining paper should be removed progressively. *Paediatric population:* Courses should be limited to five days and tight coverings should not be used. If irritation or infection develops, remove tape, and consult a physician.
Fludroxycortide Tape is waterproof. Cosmetics may be applied over the tape.

Contraindications: Chicken pox; vaccinia; tuberculosis of the skin; hypersensitivity to any of the components; facial rosacea, acne vulgaris, perioral dermatitis, perianal and genital pruritus; dermatoses in infancy including eczema, dermatitic napkin eruption, bacterial (impetigo), viral (herpes simplex) and fungal (candida or dermatophyte) infections.
Warnings and Precautions: Not advocated for acute and weeping dermatoses. Local and systemic toxicity of medium and high potency topical corticosteroids is common, especially following long-term continuous use, continued use on large areas of damaged skin, flexures and with polythene occlusion. Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression. Long-term continuous therapy should be avoided in all patients irrespective of age. Application under occlusion should be restricted to dermatoses in very limited areas. If used on the face, courses should be limited to five days and occlusion should not be used. In the presence of skin infections, the use of an appropriate antifungal or antibacterial agent should be instituted. Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered. For children, administration of topical corticosteroids should be limited to the least amount compatible with an effective therapeutic regimen. Children may absorb proportionally larger amounts of topical corticosteroids and thus may be more susceptible to systemic toxicity.

Pregnancy and Lactation: Use in pregnancy only when there is no safer alternative and when the disease itself carries risks for mother and child. Caution should be exercised when topical corticosteroids are administered to nursing mothers.

Undesirable Effects: The following local adverse reactions may occur with the use of occlusive dressings: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acne form eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, miliaria, striae and thinning and dilatations of superficial blood vessels producing telangiectasia. Transient HPA axis suppression. Cushing's syndrome. Hyperglycaemia. Glycosuria. Adrenal suppression in children may occur. Infected skin lesions, viral, bacterial, or fungal may be substantially exacerbated by topical steroid therapy. Wound healing is significantly retarded. Local hypersensitivity reactions. Stop treatment immediately if hypersensitivity occurs. Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules.

Precautions for Storage: Store in a dry place, below 25ºC.

Pack Size and Price: Polypropylene dispenser and silica gel desiccant sachet in a polypropylene container, with a polyethylene lid, packed in a cardboard box, containing 20cm or 50cm of translucent, polythene adhesive film, 7.5cm wide, protected by a removable paper liner. 7.5cm x 20cm £16.49. 7.5cm x 50cm £23.75
Legal Category: POM
Marketing Authorisation Number: PL 00551/0014 **Marketing Authorisation Holder:** Typharm Ltd., 14D Wendover Road, Rackheath Industrial Estate, Norwich, NR13 6LH. Tel: 01603 722480, Fax: 01603 263804.
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Typharm Limited on 02037 694160.