Long-form EI (for more information, see rule 41 of the PAGB professional code)

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 McNeil Products Limited on 01344 864 042.

Daktacort Hydrocortisone Cream (miconazole nitrate 2% w/w and hydrocortisone acetate) Product Information:

Presentation:
White, homogeneous, odourless cream containing miconazole nitrate 2% w/w and hydrocortisone acetate equivalent to hydrocortisone 1% w/w.

Indications:
Athlete's foot and candidal intertrigo where there are co-existing symptoms of inflammation. *Dermatophytes,* pathogenic yeasts (e.g., *Candida* spp.) and many Gram-positive bacteria including most strains of *Streptococcus* and *Staphylococcus* are susceptible to miconazole. The properties of Daktacort Hydrocortisone Cream indicate it particularly for the initial stages of treatment. Once the inflammatory symptoms have disappeared, treatment can be continued with Daktarin Cream or Powder.

Dosage and Administration:
For topical administration. Apply the cream twice a day to the affected area. Maximum period of treatment is 7 days. Natural thinning of the skin occurs in the elderly; hence corticosteroids should be used sparingly and for short periods of time.

Contraindications:
Known hypersensitivity to miconazole or other imidazole derivatives, hydrocortisone or to any of the excipients listed in section 6.1 of the SPC. Tubercular or viral infections of the skin or those caused by Gram-negative bacteria. Use on broken skin, large areas of skin, for treatment longer than 7 days, to treat cold sores and acne, use on the face, eyes and mucous membranes. Should not be used unless prescribed by a doctor in the following: children under 10 years of age, on the ano-genital region, to treat ringworm or secondary infected conditions.

Precautions:
When used by patients taking oral anticoagulants, the anticoagulant effect should be carefully monitored. Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with Daktacort Hydrocortisone Cream and other miconazole topical formulations (see side effects). If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued. Cream must not come into contact with the mucosa of the eyes. Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for

referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids. Caution is advised when Daktacort Hydrocortisone Cream is to be applied to extensive surface areas or under occlusive dressings including baby napkins. Long term continuous topical corticosteroid therapy and application to the face should be avoided. Adrenal suppression can occur even without occlusion. Once the inflammatory conditions have disappeared treatment may be continued with Daktarin Cream or Daktarin powder. Serum concentrations of hydrocortisone may be higher with the use of Daktacort Hydrocortisone Cream compared with topical preparations containing hydrocortisone alone. Contact should be avoided between latex products such as contraceptive diaphragms or condoms and Daktacort Hydrocortisone Cream since the constituents of Daktacort Hydrocortisone Cream may damage the latex. Daktacort Hydrocortisone Cream can damage certain synthetic materials. Therefore, it is recommended to wear cotton underwear if this clothing comes into contact with the affected area. This medicine contains 2 mg/g of Benzoic acid (E210), which may cause local irritation. This medicine also contains 0.052 mg/g of Butylhydroxyanisole (E320) which may cause local skin reactions (e.g., contact dermatitis), or irritation to the eyes and mucous membranes.

Pregnancy and lactation:

Avoid use during pregnancy. Caution recommended during breast-feeding. Treatment of large surfaces and the application under occlusive dressing should be avoided during pregnancy and breast-feeding. Consult a doctor prior to use.

Side-effects:

Uncommon: skin irritation, skin burning sensation, urticaria, pruritis and irritability.

Frequency Not Known: anaphylactic reaction, hypersensitivity, blurred vision, angioedema, rash, contact dermatitis, erythema, skin inflammation, skin hypopigmentation and application site reaction.

RRP (ex-VAT): 15g tube, £5.69

Legal category: P

PL Holder: McNeil Products Limited, 50 -100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK

PL Numbers: 15513/0303

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