SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Daktacort Hydrocortisone Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Miconazole nitrate 2% w/w; Hydrocortisone acetate equivalent to hydrocortisone 1% w/w.

Excipients with known effect:

2 mg/g of benzoic acid (E210)
0.052 mg/g of butylhydroxyanisole (E320).

For the full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Cream.

White, homogeneous, odourless cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Athlete's foot and candidal intertrigo where there are co-existing symptoms of inflammation.

Organisms which are susceptible to miconazole are dermatophytes and pathogenic yeasts (eg, *Candida* spp.). Also many Gram-positive bacteria including most strains of *Streptococcus* and *Staphylococcus*.

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 Daktarin powder.

4.2 Posology and method of administration

For topical administration

Apply the cream twice a day to the affected area, rubbing in gently until the cream has been absorbed by the skin.

The maximum period of treatment is 7 days.

Elderly

Natural thinning of the skin occurs in the elderly, hence corticosteroids should be used sparingly and for short periods of time.

4.3 Contraindications

Known hypersensitivity to miconazole or other imidazole derivatives, hydrocortisone or to any of the excipients listed in section 6.1.

Tubercular or viral infections of the skin or those caused by Gram-negative bacteria.

Daktacort Hydrocortisone Cream should not be used in the following conditions:

- If the skin is broken
- On large areas of skin
- Used for longer than 7 days
- To treat cold sores and acne
- Use on the face, eyes and mucous membranes
- Children under 10 years of age, unless prescribed by a doctor
- On the ano-genital region unless prescribed by a doctor
- To treat ringworm unless prescribed by a doctor
- To treat secondary infected conditions unless prescribed by a doctor

4.4. Special Warnings and Special Precautions for Use

When Daktacort Hydrocortisone Cream is 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 Adverse reactions).

If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued.

Daktacort Hydrocortisone 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.

As with any topical corticosteroid, caution is advised when Daktacort Hydrocortisone Cream is to be applied to extensive surface areas or under occlusive dressings including baby napkins; similarly application to the face should be avoided.

Long term continuous topical corticosteroid therapy 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 (see section 4.1).

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.

Miconazole administered systemically is known to inhibit CYP3A4/2C9, which can lead to prolonged effects of warfarin or other vitamin K antagonists. While systemic absorption is limited with topical formulations, the concomitant use of Daktacort Hydrocortisone Cream and warfarin or other vitamin K antagonists should be done with caution and the anticoagulant effect should be carefully monitored and titrated. Patients should be advised of the symptoms of bleeding events and to immediately stop treatment with miconazole and seek medical advice should they occur (see section 4.5).

4.5. Interactions with other Medicaments and other forms of Interaction

Miconazole administered systemically is known to inhibit CYP3A4/2C9. Due to the limited systemic availability after topical application, clinically relevant interactions are rare. However, in patients on warfarin or other vitamin K antagonists, caution should be exercised and anticoagulant effect should be monitored.

Miconazole is a CYP3A4 inhibitor that can decrease the rate of metabolism of hydrocortisone. Serum concentrations of hydrocortisone may be higher with the use of Daktacort Hydrocortisone Cream compared with topical preparations containing hydrocortisone alone.

4.6 Fertility, pregnancy and lactation

Pregnancy
Clinical data on the use of Daktacort Hydrocortisone Cream in pregnancy are limited. Corticosteroids are known to cross the placenta and consequently can affect the foetus (See Section 5.3). Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of these findings to humans has not been established.

As a precautionary measure, it is preferable to avoid the use of Daktacort Hydrocortisone during pregnancy. Treatment of large surfaces and the application under occlusive dressing should be avoided during that time.

Breastfeeding
There are no adequate and well-controlled studies on the topical administration of Daktacort Hydrocortisone Cream during lactation. It is not known whether concomitant topical administration of Daktacort Hydrocortisone Cream to the skin could result in sufficient systemic absorption to produce detectable quantities of hydrocortisone and miconazole in breast milk in humans. Caution is recommended during breast-feeding. Treatment of large surfaces and the application under occlusive dressing should be avoided during that time.

A risk to the newborn child cannot be excluded.

4.7 Effects on ability to drive and use machines

This medicine has no influence on the ability to drive and use machines.

4.8 Undesirable effects

The safety of Daktacort Hydrocortisone Cream was evaluated in 480 patients who participated in 13 clinical trials (six double-blind and seven open-label trials) of Daktacort Hydrocortisone Cream. These studies examined patients from 1 month to 95 years of age with infections of the skin caused by dermatophytes or *Candida* species in which inflammatory symptoms were prominent.

All patients
No adverse drug reactions (ADRs) were reported by ≥ 1% of the 480 Daktacort Hydrocortisone Cream-treated patients (adult and paediatric patients combined).

The frequency categories use the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to < 1/1,000); very rare (<1/10,000) and not known (cannot be estimated from the available clinical trial data).

Of the three ADR's identified from the 13 clinical trials of Daktacort Hydrocortisone Cream, skin irritation was reported in one clinical trial that included patients aged 17 to 84 years, skin burning sensation in two clinical trials that included patients aged 13 to 84 years, and irritability in one clinical trial of infants aged 1 to 34 months.

Paediatric population
The safety of Daktacort Hydrocortisone Cream was evaluated in 63 paediatric patients (1 month to 14 years of age) who were treated with Daktacort Hydrocortisone Cream in 3 of the 13 clinical trials noted above. One ADR term (irritability) was reported in these 3 trials. The frequency of irritability in Daktacort Hydrocortisone Cream-treated paediatric patients was common (3.2%).

All events of irritability occurred in one clinical trial of infants (aged 1 to 34 months) with napkin dermatitis. The frequency, type and severity of other ADRs in paediatric patients are expected to be similar to those in adults.

Table 1: Adverse Drug Reactions in Adult and Paediatric Patients Treated with Daktacort Hydrocortisone Cream

System Organ Class	**Adverse Drug Reactions**	
	Frequency Category	
	Uncommon (≥1/1,000 to <1/100)	**Not known**
Immune System Disorders		Anaphylactic reaction, Hypersensitivity
Eye disorders		Vision, blurred (see also section 4.4)
Skin and Subcutaneous Tissue Disorders	Skin irritation, Skin burning sensation. Urticaria, Pruritis	Angioedema, Rash, Contact dermatitis, Erythema, Skin inflammation, Skin hypopigmentation, Application site reaction
General Disorders and Administration Site Conditions	Irritability	

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

Prolonged and excessive use can result in skin irritation, which usually disappears after discontinuation of therapy. Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Imidazole and triazole derivatives, combinations, ATC code: D01AC20.

Miconazole nitrate is active against dermatophytes and pathogenic yeasts and many Gram-positive bacteria.

The clinical efficacy of miconazole has been demonstrated against dermatophytes, *Candida* spp., *Aspergillus* spp., dimorphous fungi, *Cryptococcus neoformans*, *Malassezia* spp. and *Torulopsis glab*rata. Miconazole also has an antibacterial activity against some gram-positive bacilli and cocci.

Hydrocortisone is an anti-inflammatory steroid. Its anti-inflammatory action is due to reduction in the vascular component of the inflammatory response, suppression of migration of polymorphonuclear leukocytes, and reversal of increased capillary permeability. The vasoconstrictor action of hydrocortisone may also contribute to its anti-inflammatory activity.

5.2 Pharmacokinetic properties

Absorption

Miconazole remains in the skin after topical application for up to 4 days. Systemic absorption of miconazole is limited, with a bioavailability of less than 1% following topical application of miconazole. Plasma concentrations of miconazole and/or its metabolites were measurable 24 and 48 hours after application. Approximately 3% of the dose of hydrocortisone is absorbed after application on the skin.

Distribution

Absorbed miconazole is bound to plasma proteins (88.2%) and red blood cells (10.6%). More than 90% of hydrocortisone is bound to plasma proteins.

Metabolism and elimination

The small amount of miconazole that is absorbed is eliminated predominantly in faeces as both unchanged drug and metabolites over a four-day post-administration period. Smaller amounts of unchanged drug and metabolites also appear in urine.

The half-life of hydrocortisone is about 100 minutes. Metabolism takes place in the liver and tissues and the metabolites are excreted with the urine, mostly as glucuronides, together with a very small fraction of unchanged hydrocortisone.

5.3 Preclinical safety data

Preclinical data on the drug product (miconazole nitrate + hydrocortisone) revealed no special hazard for humans based on conventional studies of ocular irritation, dermal sensitisation, single dose oral toxicity, primary dermal irritation toxicity, and 21-day repeat dose dermal toxicity. Additional preclinical data on the individual active ingredients in this drug product reveal no special hazard for humans based on conventional studies of local irritation, single and repeated dose toxicity, genotoxicity, and for miconazole toxicity to reproduction. Miconazole has shown no teratogenic effects but is foetotoxic at high oral doses. Reproductive effects (foetotoxicity, reduced weight gain) and developmental abnormalities, specifically craniofacial effects including cleft palate have been reported with hydrocortisone in various animal models.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 6-32 stearate and glycol stearate
Oleoyl macrogolglycerides
Liquid paraffin
Butylhydroxyanisole (E320)
Benzoic acid (E210)
Disodium edetate
Sodium hydroxide solution
Purified water

6.2 Incompatibilities

Contact should be avoided between latex products such as contraceptive diaphragms or condoms and Daktacort Hydrocortisone cream since the constituents of Daktacort may damage the latex.

6.3 Shelf life

2 years

6.4 Special precautions for storage

None

6.5. Nature and Contents of Container

Tube formed from aluminium/PE laminate with a polypropylene screw cap.
Each tube contains 15g cream.

6.6 Special precautions for disposal <and other handling>

No special requirements for disposal

Any unused medicinal products or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
50 – 100 Holmers Farm Way
High Wycombe
Buckinghamshire
HP12 4EG
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0303

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/02/2009

10 DATE OF REVISION OF THE TEXT

07/10/2025