SUMMARY OF THE PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Cortimyk 20 mg/g + 10 mg/g cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 gram of cream contains 20 mg miconazole nitrate and 10 mg hydrocortisone.

Excipients with known effect: benzoic acid 2 mg and butylhydroxyanisole 0.055 mg.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Tinea (*dermatophytoses caused by Trichophyton, Epidermophyton and Microsporum* species) and cutaneous candidiasis with inflammatory elements and/or where itching is troublesome.

4.2 Posology and method of administration

The cream is thinly applied to the infected skin areas twice a day. Rub the cream into the skin with your finger until it has been completely absorbed. In the event of athlete's foot the feet should be washed and dried carefully before application. Once the inflammatory symptoms have disappeared, treatment can be continued with just one antimycotic, e.g. miconazole nitrate 20 mg/g cream. The duration of therapy varies from 2 to 6 weeks depending on the localization and the severity of the lesion. To avoid recurrence the treatment with Cortimyk (or subsequently with miconazole nitrate 20 mg/g cream) should continue for at least one week after the symptoms have disappeared.

Paediatric population
In infants and children, caution is advised when Cortimyk is applied to large body areas or under occlusive dressings, including diapers. In infants, long-term use of topical corticosteroids should be avoided (see also special warnings and precautions for use).

The elderly
Thinning of the skin occurs naturally in the elderly. Corticosteroids should therefore be used sparingly and for short periods of time.

Method of administration
For cutaneous use only.

4.3 Contraindications

Hypersensitivity to miconazole, other imidazole derivatives, hydrocortisone or to any of the excipients listed in section 6.1. Herpes simplex, vaccinia, all forms of varicella and tuberculous skin disease.

4.4 Special warnings and special precautions for use

Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with miconazole local formulations. If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued. Cortimyk must not come into contact with the mucosa of the eyes.

Long-term treatment (> 4-6 weeks) with Cortimyk should be avoided since the cream contains corticosteroids.

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 Cortimyk 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).

Visual disturbance
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.

Paediatric population
As with any local treatment with corticosteroids, caution is advised with infants and children when Cortimyk is to be applied to large body areas or under occlusive dressings, including diapers. Application to the face should also be avoided. During long-term treatment of severe eczema on large body areas in small children, the risk of systemic effects should be taken into account. Adrenal suppression can occur even without the use of occlusive dressings.

Cortimyk contains benzoic acid which may be mildly irritant to the skin, eyes and mucous membranes. Benzoic acid may increase the risk of jaundice (yellowish skin and eyes) in newborn infants (up to 4 weeks old). Cortimyk contains butylhydroxyanisole which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

As Cortimyk can damage certain synthetic materials, it is recommended to wear cotton underwear if this clothing comes into contact with the treated area.

Avoid contact between products containing latex (e.g. latex diaphragms or latex condoms), since the ingredients of Cortimyk may damage latex products.

4.5 Interaction with other medicinal products 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. The effect and side effects of certain other

medicines (e.g. oral antidiabetic medication and phenytoin) may be intensified when co-administered with miconazole; caution should be exercised.

Miconazole is a CYP3A4 inhibitor that can reduce the metabolism of hydrocortisone. Serum concentrations of hydrocortisone may be higher with the use of products containing miconazole compared with topical preparations containing hydrocortisone alone.

4.6 Fertility, pregnancy and lactation

Pregnancy
Caution is recommended if used during pregnancy.
Treatment of large body areas and application under occlusive dressings should be avoided.
Miconazole has not been shown to be teratogenic in animals but has been shown to be embryotoxic at maternally toxic doses. In animals, corticosteroids are known to cross the placenta and hence affect the foetus.

Breast-feeding
There are no adequate and well-controlled studies of the topical use of Cortimyk during breast-feeding. It is not known whether topical administration of Cortimyk to the skin can result in sufficient systemic absorption to produce measurable quantities of hydrocortisone and miconazole in human breast milk. Application on the breasts should be avoided. Treatment of large areas and the application of occlusive dressings should be avoided during this time.

Fertility
The effect of the combination of miconazole and hydrocortisone on human fertility has not been assessed.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Side effects can be expected to occur in about 1% of patients. The three most common undesirable effects identified in clinical trials were skin irritation, a burning sensation of the skin and irritability.

Skin and subcutaneous tissue disorders	
Uncommon (≥1/1,000 to ≤1/100):	Skin irritation, skin burning sensation, urticaria, pruritus
Not known:	Angioedema, rash, contact dermatitis, erythema, skin inflammation, hypopigmentation, reaction at the application site
Eye disorders	
Not known:	Vision, blurred (see also section 4.4)
Immune system disorders	
Not known:	Anaphylactic reaction, hypersensitivity
General disorders and administration site conditions	
Uncommon ((≥1/1,000 to ≤1/100):	Irritability

Paediatric population

The safety of miconazole cream was evaluated in 63 paediatric patients (between 1 month and 14 years of age), who were treated with miconazole cream in 3 of the 13 aforementioned clinical trials. One undesirable effect (irritability) was reported in all the trials. The frequency of irritability in paediatric patients treated with miconazole cream was 3.2%. All cases of irritability occurred in one clinical trial in infants (aged 1 to 34 months) with diaper eczema. The frequency, type and severity of other undesirable effects in paediatric patients are expected to be similar to those in adults.

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 national reporting system listed in Appendix V

4.9 Overdose

Excessive use can lead to skin irritation, the symptoms of which usually disappear when treatment is discontinued. Locally applied corticosteroids can be absorbed in sufficient amounts to cause systemic effects.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Broad-spectrum antimycotic + mild glucocorticoid (Group I), ATC code: D01A C20

Cortimyk cream contains the active components miconazole and hydrocortisone. Miconazole is an imidazole derivative with a fungicidal effect both *in vitro* and *in vivo* against most pathogenic fungi. The spectrum of action includes dermatophytes *(Trichophyton, Epidermophyton* and *Microsporum* species*), Candida spp.* and *Pityrosporum spp.*

Miconazole inhibits biosynthesis of ergosterol in the fungus and thus changes other lipids' composition in the cell membrane, leading to necrosis in the fungal cell.

Hydrocortisone is a Group I corticosteroid with an anti-inflammatory and antipruritic effect.

Cortimyk does not discolour skin and clothes and can be washed off with soap and water.

5.2 Pharmacokinetic properties

Miconazole is absorbed to a very small degree when locally applied.

Hydrocortisone penetrates the skin well and is absorbed to various degrees depending on the type and localisation of the infection. Hydrocortisone is metabolised in the liver and the tissues, the metabolites are eliminated via the urine together with a small amount of hydrocortisone in unchanged form.

5.3 Preclinical safety data

There are no preclinical data considered relevant to the safety assessment beyond what has already been taken into consideration in other parts of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pegoxol 7 stearate, oleoyl macrogolglycerides, light liquid paraffin, anhydrous disodium edetate, benzoic acid, butylhydroxyanisole and water.
Sodium hydroxide and hydrochloric acid for adjustment of the pH.

6.2 Incompatibilities

Not relevant.

6.3 Shelf-life

18 months.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and content of container

Aluminium laminate tube, 20 g, 2 x 20 g and 50 g.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

12627

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1995-11-08/2010-11-08

10 DATE OF REVISION OF THE TEXT

2025-09-15