SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Loceryl 0.25% w/w cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Loceryl cream contains 0.25% w/w amorolfine in the form of hydrochloride. Amorolfine is chemically described as *cis*-4-[(RS)-3[4-(1,1-Dimethylpropyl)phenyl]-2-methylpropyl]-2,6-dimethylmorpholine.

Amorolfine hydrochloride	HSE	0.279	w/w
(equivalent to 0.25% w/w base)			

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Dermatomycoses caused by dermatophytes: tinea pedis (athlete's foot), tinea cruris, tinea inguinalis, tinea corporis, tinea manuum. Pityriasis versicolor.

4.2 Posology and method of administration

Dermatomycoses

Cream: To be applied to affected skin areas once daily following cleansing (in the evening).

The treatment should be continued without interruption until clinical cure, and for 3 - 5 days thereafter. The required duration of treatment depends on the species of fungi and on the localisation of the infection. In general, treatment should be continued for at least two to three weeks. With foot mycoses, up to six weeks of therapy may be necessary.

Elderly

There are no specific dosage recommendations for use in elderly patients.

Children

There are no specific dosage recommendations for children owing to the lack of clinical experience available to date.

4.3 Contraindications

Loceryl cream must not be reused by patients who have shown hypersensitivity to the active substance or to any of the excipients.

No experience exists of use during pregnancy and nursing, therefore, the use of Loceryl should be avoided during pregnancy and lactation.

4.4 Special warnings and precautions for use

Avoid contact of Loceryl cream with eyes, ears and mucous membranes.

This medicinal product contains stearyl alcohol which may cause local skin reaction (e.g. contact dermatitis)

Owing to the lack of clinical experience available to date, the use of Loceryl 0.25% cream in children is not recommended.

A systemic or local allergic reaction could possibly occur after use of this product. If this happens, the product should be stopped immediately and medical advice should be sought.
Remove the product carefully by cleaning the skin.
The product should not be reapplied.

4.5 Interaction with other medicinal products and other forms of interaction

There are no specific studies involving concomitant treatment with other topical medicines. Use of nail varnish or artificial nails should be avoided during treatment.

4.6 Fertility, pregnancy and lactation

Reproductive toxicology studies showed no evidence of teratogenicity in laboratory animals but embryotoxicity was observed at high oral doses. The systemic absorption of amorolfine during and after topical administration is very low and therefore the risk to the human foetus appears to be negligible. Loceryl Cream should not be used during pregnancy and/or lactation unless clearly necessary. Breast-feeding women must not use the cream in the breast area.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Adverse drug reactions are rare and mostly mild in nature.

System Organ Class	Frequency	Adverse drug reaction
Immune system disorders	Unknown frequency*	Hypersensitivity (systemic allergic reaction)*
Skin and subcutaneous tissue disorders	Rare (≥1/10 000, <1/1000)	Skin Irritation, erythema, pruritus, skin burning sensation
	Unknown frequency*	Dermatitis contact *

* post marketing experience

4.9 Overdose

Accidental oral Ingestion

Loceryl is for topical use. In the event of accidental oral ingestion, an appropriate method of gastric emptying may be used.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antifungals for topical use ATC code: D01AE16

Loceryl is a topical antimycotic. Amorolfine belongs to a new chemical class, and its fungicidal action is based on an alteration of the fungal cell membrane targeted primarily on sterol biosynthesis. The ergosterol content is reduced, and at the same time unusual sterically nonplanar sterols accumulate.

Amorolfine is a broad spectrum antimycotic. It is highly active (MIC < 2mcg/ml) *in vitro* against

yeasts:	*Candida, Cryptococcus, Malassezia*
dermatophytes:	*Trichophyton, Microsporum, Epidermophyton*
moulds:	*Hendersonula, Alternaria, Scopulariopsis*
dematiacea:	*Cladosporium, Fonsecaea, Wangiella*
dimorphic fungi:	*Coccidioides, Histoplasma, Sporothrix*

With the exception of *Actinomyces*, bacteria are not sensitive to amorolfine. *Propionibacterium acnes* is only slightly sensitive.

5.2 Pharmacokinetic properties

Amorolfine from cream penetrates into the stratum corneum. Nevertheless, systemic absorption is extremely low during and after therapeutic use.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyoxyl 40 stearate, stearyl alcohol, paraffin liquid, white soft paraffin, carbomer, sodium hydroxide, disodium edetate, 2 phenoxyethanol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Loceryl cream should be stored below 30°C.

6.5 Nature and contents of container

20 g collapsible aluminium tube, sealed with an aluminium membrane and fitted with a plastic screw cap.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 10590/0041

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10 DATE OF REVISION OF THE TEXT

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