Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Canesten HC 1% w/w + 1% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 10 mg clotrimazole (1% w/w) and 11.2 mg hydrocortisone acetate (equivalent to 10 mg hydrocortisone (1% w/w)).
Excipient(s) with known effect: each gram of cream contains 100 mg cetostearyl alcohol and 20 mg benzyl alcohol.
For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Cream.
A white to pale yellow cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Canesten HC Cream is a combination of an antifungal and a corticosteroid, both absorbable through broken skin. It is indicated for the topical treatment of skin infections due to superficial dermatophytes, yeasts, moulds and other fungi sensitive to clotrimazole where co-existing symptoms of inflammation, e.g. itching, require rapid relief.

4.2 Posology and method of administration

Canesten HC Cream should be thinly and evenly applied to the affected area twice daily and rubbed in gently.

Treatment should be continued for no more than 7 days.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

The following contra-indications apply to the hydrocortisone component: specific bacterial skin diseases (syphilis, tuberculosis), chicken pox, vaccination reactions, perioral dermatitis, viral skin diseases (e.g. herpes simplex, rosacea, shingles), use on broken skin, acne.

4.4 Special warnings and precautions for use

All possibly infected areas should be treated at the same time.

Because of its corticosteroid content, Canesten HC should not be applied:

- To large areas (more than 10% of the body surface)
- In long term continuous therapy
- Under occlusive dressing, particularly in infants and children, because of the possibility of

adrenocortical suppression.

This product contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis) and benzyl alcohol which may cause mild local irritation.

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.

4.5 Interaction with other medicinal products and other forms of interaction

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

4.6 Fertility, pregnancy and lactation

Fertility:

No human studies of the effects of clotrimazole on fertility have been performed, however, animal studies have not demonstrated any effects of the drug on fertility. No data is available on the effects of topically applied hydrocortisone.

Pregnancy:

There is a limited amount of data from the use of clotrimazole or hydrocortisone in pregnant women. As a precautionary measure, it is recommended not to apply Canesten HC for long period during pregnancy particularly in the first three months, and it is preferable to avoid the use of Canesten HC cream during the first trimester of pregnancy.

Lactation:

No data on hydrocortisone is available, but topically applied hydrocortisone is unlikely to cause systematic effects due to the low percutaneous penetration. However, cutaneous absorption may be increased under certain circumstances, such as with use of occlusive dressing, the degree of skin damage, and the size of the treated area.

Breast-feeding should be discontinued during treatment with Canesten HC cream.

4.7 Effects on ability to drive and use machines

The medication has no or negligible influence on the ability to drive or use machinery.

4.8 Undesirable effects

The following adverse reactions have been identified during post-approval use of Canesten HC cream. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency.

Immune System Disorders:
allergic reaction (syncope, hypotension, dyspnea, urticaria)

Eye disorders
blurred vision may occur, however the frequency is not known (see section 4.4).

Skin and Subcutaneous Tissue Disorders:
discomfort/pain, edema, erythema, hypertrichosis, irritation, pruritus, rash, secondary infection and acneiform symptoms, skin atrophy, skin discoloration, skin striae, stinging/burning, teleangiectasis

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

In the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungals for topical use – imidazole and triazole derivates, combinations

ATC Code: D01A C20
Canesten HC is a combination of clotrimazole and hydrocortisone.

Mechanism of Action

Clotrimazole
Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.

Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, moulds, etc.

Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062 – 8.0) microg/ml substrate. The mode of action of clotrimazole is fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. In vitro activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.

In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (streptococci/staphylococci/Gardnerella vaginalis) and gram-negative microorganisms (Bacteroides). It has no effect on lactobacilli.

In vitro, clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci – with the exception of enterococci – in concentrations of 0.5 – 10 microg/ml substrate.Primary resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

Hydrocortisone
Hydrocortisone is a weak corticosteroid with both glucocorticoid and to a lesser extent mineralocorticoid activity. As the active ingredient in a topical cream it exerts anti-inflammatory, antipruritic, antiexudative and antiallergic effects.

Hydrocortisone exerts an anti-inflammatory, immunosuppressive, antimitotic (antiproliferative), antiallergic, antipruriginous and vasoconstrictive effect on the skin. Thus, in addition to the elimination of inflammation and pruritis, a normalisation of keratinisation, inhibition of excess fibroblast activity and epidermopoiesis, degradation of pathological metabolic products and inhibition of acantholysis are achieved.

5.2 Pharmacokinetic properties

Clotrimazole:
Pharmacokinetic investigations after dermal application have shown that clotrimazole is practically not absorbed from intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.01 microg/ml, reflecting that clotrimazole applied topically does not lead to measurable systemic effects or side effects.

Hydrocortisone:

Dermal absorption of hydrocortisone depends on the thickness and condition of the skin. In healthy skin no systemic effects of corticoids have been observed after local application.

However, in the case of inflamed or damaged skin, cutaneous absorption may be increased depending on the site of application, use of occlusive dressings, the degree of skin damage, and size of the treated area. Systemic effects can not be ruled out under such conditions.

An increase in the skin temperature or moisture content, e.g. in skin folds or under an occlusive dressing, also promotes absorption. In infants and small children the epidermal barrier is still poorly developed, which facilitates transcutaneous uptake of drugs.
The occurrence of systemic effects depends partly on the dose and, to a much greater extent, on the duration of treatment.

More than 90% of the hydrocortisone absorbed is bound to plasma proteins. Hydrocortisone is metabolised in the liver and tissues, and the metabolites are excreted with urine. The biological half-life is approximately 100 minutes.

No relevant absorption of hydrocortisone is expected after its use for a short period on limited skin inflamed areas.

5.3 Preclinical safety data

Clotrimazole:
Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction and development.

Hydrocortisone:
As an adrenocortical hormone, hydrocortisone is classified as relatively non-toxic for topical use. Teratogenic effects of high doses of corticosteroids such as cleft palate formation, growth retardation, and fetal mortality, etc. were observed after systemic use in animal studies; there are no data on teratogenic effects after dermal use.

Clotrimazole plus hydrocortisone:
Nonclinical data based on acute and repeated dose toxicity studies reveral no special hazard to humans. In a 90-day repeated dose dermal study, effects were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Cetostearyl alcohol
Medium chain triglycerides
Tricetereth-4 phosphate
Sodium hydroxide and hydrochloric acid (for pH adjustment)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Sealed: 24 months
After opening: 6 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tube with internal lacquer coating and HDPE screw-on cap in cardboard carton.
Pack sizes available: 30g pack.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

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9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 28th June 2023

10 DATE OF REVISION OF THE TEXT

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