

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Canesten HC Cream

Clotrimazole 1.0% w/w

Hydrocortisone 1.0% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The cream contains 1% w/w of clotrimazole and 1% w/w of hydrocortisone

Excipients: also contains cetostearyl alcohol.

For a full list of excipients, see 6.1

3 PHARMACEUTICAL FORM

Cream

Product imported from the UK:

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 any of the ingredients in this medicine.

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 larger 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 reaction (e.g contact dermatitis).

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

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this to humans has not been established. In animal studies, clotrimazole has not been associated with teratogenic effects but, following oral administration of high doses to rats, there was evidence of foetotoxicity. The relevance of this effect to topical administration in humans is not known.

However, clotrimazole has been used in pregnant patients for over a decade without attributable adverse effects. It is therefore recommended that Canesten HC Cream should be used in pregnancy and lactation only when considered essential by the clinician.

4.7 Effects on ability to drive and use machines

None applicable.

4.8 Undesirable effects

Side-effects include local irritation or burning. If this is severe, treatment should be discontinued. Hypersensitivity reactions may occur.

After use on large areas (more than 10% of the body surface) and/or after long-term use (longer than 2-4 weeks) or use under occlusive dressings, local skin alterations such as skin atrophy, telangiectasis, hypertrichosis, striations hypopigmentation, secondary infection and acneiform symptoms may occur.

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 becomes apparent (e.g. dizziness, nausea or vomiting).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D01A C20.

Canesten HC is a combination of clotrimazole, which is an imidazole derivative, and hydrocortisone, which is a glucocorticoid. Canesten HC is a broad spectrum antimycotic.

Mechanism of Action

Clotrimazole

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

Hydrocortisone

Hydrocortisone is a weak corticosteroids 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.

Pharmacodynamic Effects

Canesten HC has a broad antimycotic spectrum of action *in vitro* and *in vivo*, which includes dermatophytes, yeast, moulds, etc.

Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-4(-8) 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 *Trichomonas Vaginalis*, gram-positive microorganisms (Streptococci/Staphylococci) and gram-negative microorganisms (*Bacteroides/Gardnerella Vaginalis*). 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 0.05- 10 microg/ml substrate and exerts a trichomonacidal action at 100 microg/ml.

Primary resistance 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 exerts an anti-inflammatory, immunosuppressive, antimitotic (antiproliferative), antipruriginous and vasoconstrictive effect on the skin. Thus, in addition to the elimination of inflammatory 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 investigation after dermal application has 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

There are no preclinical safety data of relevance to the prescriber which are additional to those already included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Cetostearyl alcohol
Medium chain triglycerides
Triceteareth-4 phosphate
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.
Store in original carton

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.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B & S Healthcare
Unit 4, Bradfield Road
Ruislip
Middlesex HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/150/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st April 2011

10 DATE OF REVISION OF THE TEXT