Canesten®

Canesten® Plus Antifungal Cream
For external use only

Product Description
Canesten® Plus Antifungal Cream is a white cream packaged in an aluminum tube with PE (polyethylene) screw cap. Canesten® Plus Antifungal Cream is available in tubes of 15 g.

What are the ingredients in Canesten® Plus Antifungal Cream?
100g Canesten® Plus Antifungal Cream contains 1 g clotrimazole and 1 g hydrocortisone (as 1.12 g hydrocortisone acetate, micronised) as active ingredients.

Canesten® Plus Antifungal Cream also contains benzyl alcohol, cetostearyl alcohol, tricetareth-4-phosphate, triglycerides medium-chain, sodium hydroxide (or hydrochloric acid) and water as excipients.

Canesten® Plus Antifungal Cream does not contain colours or fragrances.

What is Canesten® Plus Antifungal Cream used for?
Canesten® Plus Antifungal Cream is a topical antifungal cream used to treat skin infections with co-existing symptoms of inflammation, e.g. itching, which rapid symptom relief is desired.

Canesten® Plus Antifungal Cream is effective against:
- Dermatomycoses caused by dermatophytes (e.g. athlete's foot), yeasts (e.g. candida intertrigo), moulds, and other fungi
- Infections of the vaginal areas caused by yeast fungi (candida vulvitis); inflammation of the penis area caused by yeast fungi (candida balanitis)
- Skin diseases superinfected with organisms sensitive to clotrimazole

If you are not sure whether you should start using Canesten® Plus Antifungal Cream, talk to your doctor or pharmacist.

How should Canesten® Plus Antifungal Cream be used?
Apply Canesten® Plus Antifungal Cream thinly to the affected skin area once a day or twice a day (in the morning and evening) and rub it in gently.

Use Canesten® Plus Antifungal Cream only until inflammation, itching and redness have subsided, and for a maximum of 7 days (unless otherwise directed by your doctor). Then continue treatment with an Antifungal Cream without hydrocortisone (eg. Canesten® cream 1%) for 14 days after symptoms have subsided to avoid recurrence of the infection.

How does Canesten® Plus Antifungal Cream work?
Canesten® Plus Antifungal Cream is a broad spectrum anti-fungal and anti-inflammatory cream. It contains two active ingredients; clotrimazole and hydrocortisone. Clotrimazole belongs to a group of medicines called imidazole antifungals which are used to treat fungal skin infections. Hydrocortisone is a mild steroid which reduces the swelling, redness and itching associated with inflammation of the skin.

When should you not use Canesten® Plus Antifungal Cream?
Do not use Canesten® Plus Antifungal Cream if:
- You are allergic or hypersensitive to any of the ingredients in this product (cetostearyl alcohol may cause local skin reactions, e.g. contact dermatitis)
- The affected area of skin is broken
- You have other conditions affecting the skin (e.g. acne, rosacea, perioral dermatitis, lues/syphilis, tuberculosis, etc.)
- You have a viral skin condition (e.g. cold sores, herpes simplex, chicken pox, etc.)
- You currently have skin reaction as a result of a vaccination

What precautions should you note while using Canesten® Plus Antifungal Cream?
1) Because of its corticosteroid content, Canesten® Plus should not be:
   - Applied to large areas (more than 10% of the body surface)
   - Applied under occlusive dressings (such as nappies and bandages) because this may increase absorption
   - Used for a long period during pregnancy particularly in the first three months.
   - Used in long term continuous therapy
2) Canesten® Plus Antifungal Cream contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).
3) Do not use on children under 2 years of age except under the advice and supervision of a doctor.
4) Increased systemic absorption as a result of the use of nappies or long term continuous therapy may result in adrenocortical suppression in infants and children.
5) The effectiveness and safety of latex products such as condoms and diaphragms may be reduced by Canesten® Plus Antifungal Cream when applied on the genital area (women: labia and adjacent area of the vulva; men: prepuce and glans of the penis). The effect is temporary and may occur only during treatment.
6) As with all other medications, keep Canesten® Plus Antifungal Cream out of the reach of children.
7) Canesten® Plus Antifungal Cream should not come into contact with your 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.
8) Canesten® Plus Antifungal Cream is meant for external use only; do not swallow.

Does Canesten® Plus Antifungal Cream exert any effects on fertility, pregnancy or lactation?
Fertility
No human studies on 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. Animal studies with clotrimazole do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Studies in animals have shown reproductive effects at high doses of corticosteroids after systemic use, and there is no animal data on the reproductive effects after topical use. As a precautionary measure, it is recommended not to apply Canesten® Plus Antifungal Cream for a long period during pregnancy, particularly in the first three months. It is preferable to avoid the use of Canesten® Plus Antifungal Cream during the first trimester of pregnancy, unless otherwise directed by a physician.

Lactation
Available pharmacodynamic/toxicological data in animals have shown excretion of clotrimazole/metabolites in milk after intravenous administration.

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 the use of occlusive dressings, the degree of skin damage, and the size of the treated area.

Breast-feeding should be discontinued during treatment with Canesten® Plus Antifungal Cream.

Can Canesten® Plus Antifungal Cream be used on children?
Do not use on children under 2 years of age except on the advice of a doctor. The risk of systemic absorption, and hence systemic toxicity, is greater in children due to the higher permeation properties of the skin and a larger skin surface to body weight ratio than adults. Bandages and some nappies may act as an occlusive dressing and may also increase systemic absorption.

Does Canesten® Plus Antifungal Cream exert any effects on the ability to drive and use machines?
Canesten® Plus Antifungal Cream has no or negligible influence on the ability to drive or use machinery.

What are the undesirable effects associated with the use of Canesten® Plus Antifungal Cream?
Skin reactions (such as hypersensitivity reactions, e.g. burning, stinging, edema or redness) can occasionally occur. Particularly after use on large areas (more than 10% of the body surface) and/or after long-term use (longer than 2-4 weeks) or under occlusive conditions, local skin alterations such as skin atrophy, telangiectasis, hypertrichosis, striations, hypopigmentation, secondary infection and acneform symptoms may occur.

The following adverse reactions have been identified during post-approval use of Canesten® Plus Antifungal Cream:

- Allergic reaction (skin rashes or hives, fainting, abnormally low blood pressure, difficulty breathing, shortness of breath).
- Skin and subcutaneous tissue disorders: blisters, discomfort/pain, edema (swelling), erythema (redness), irritation, peeling/exfoliation, pruritus(itch), rash, stinging/burning.
- Vision, blurred

However, as these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency. Should any undesirable effects occur, please consult your healthcare professional.

What other medicines or food should be avoided whilst taking this medicine?
There are no known interactions with other medicinal products or other forms of interactions.

What should you do in case of an overdose?
No reports are available on cases of overdose with Canesten® Plus Antifungal Cream.

Risk of overdose symptoms is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favorable to absorption) or inadvertent oral ingestion. In the case of overdose, there is no specific antidote.

However, in the event of an overdose or accidental ingestion, seek medical help immediately. Take this leaflet with you and any other medicine packaging to show what you are taking or have taken.

When should you consult your doctor?
Consult your doctor if you:

- Experience no improvement of symptoms even after using Canesten® Plus Antifungal Cream for about 7 days
- Experience any worsening of symptoms
- Experience hypersensitivity to Canesten® Plus Antifungal Cream
- Have allergies to any other medicine or any other substances such as foods, preservatives or colours
- Have cuts or abrasions at or near the area to be treated as the chance of unwanted effects may be increased.
- Are pregnant, suspect that you are pregnant or are breastfeeding. Your doctor will discuss with you the risks and benefits of using this product while pregnant or breastfeeding.
- Are using any other creams, ointments or lotions, or taking any medicine. This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How should you store Canesten® Plus Antifungal Cream?
Store Canesten® Plus Antifungal Cream in a cool dry place, below 30°C. Keep all medication out of reach of children. After first opening of the container, the in-use stability is 3 months. For the shelf-life, please refer to labels.

The Section Below is meant for Healthcare Professionals' Use

Pharmacodynamic Properties
Pharmacotherapeutic group: Antifungals for topical use – imidazole and triazole derivatives, combinations
ATC Codes: D01A C20

Canesten® Plus Antifungal Cream 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 µg/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 vitro clotrimazole inhibits the multiplication of Corynebacteria and grampositive cocci – with the exception of Enterococci – in concentrations of 0.5-10 µg/ml substrate.

Primarily 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 active ingredient in a topical cream it exerts antiphlogistic/anti-inflammatory, antipruritic, antiexudative and antiallergic effects.

Hydrocortisone – as other topically applied glucocorticoids – exerts an anti-inflammatory, immunosuppressive, antimitotic (antiproliferative), antipruriginous, and vasoconstrictive effect on skin. Thus, in addition to the elimination of inflammation and pruritus, a normalization of keratinization, inhibition of excess fibroblast activity and epidermopoiesis, degradation of pathological metabolic products, and inhibition of acantholysis are achieved. However, this is not a curative, but rather symptomatic treatment.

Pharmacokinetic Properties
Clotrimazole
After application on the skin, scientific trials have shown that clotrimazole is practically not absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.01 µg/ml, reflecting that clotrimazole applied topically on the skin does not lead to measurable systemic effects or undesirable effects.

Hydrocortisone
Absorption through the skin 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 cannot 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 metabolized in the liver and tissues, and the metabolites are excreted in the 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 inflammation areas.

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.

Given the limited systemic absorption of the drug after topical administration, no hazard is expected from the use of topical clotrimazole.

Hydrocortisone
Hydrocortisone is classified as relatively non-toxic for topical use.

Clotrimazole plus hydrocortisone
Non-clinical data based on acute and repeated dose toxicity studies reveal 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.

Incompatibilities
None known

End of Section meant for Healthcare Professionals

Product Registrant:
Bayer (South East Asia) Pte Ltd
2 Tanjong Katong Road,
#07-01, Paya Lebar Quarter 3,
Singapore 437161

Bayer

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