

# Canesten® Plus cream



For external use only

## Product Description

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

## What are the ingredients in Canesten® Plus cream?

100g Canesten® Plus cream contains 1 g clotrimazole and 1 g hydrocortisone (as 1.12 g hydrocortisone acetate, micronised) as active ingredients.

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

Canesten® Plus cream does not contain colours or fragrances.

## What is Canesten® Plus cream used for?

Canesten® Plus 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 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 cream, talk to your doctor or pharmacist.

## How should Canesten® Plus cream be used?

Apply Canesten® Plus 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 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 (e.g. Canesten® cream 1%) for 14 days after symptoms have subsided to avoid recurrence of the infection.

## How does Canesten® Plus cream work?

Canesten® Plus 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 cream?

Do not use Canesten® Plus 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 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 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 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 cream out of the reach of children.
- 7) Canesten® Plus cream should not come into contact with your eyes
- 8) Canesten® Plus cream is meant for external use only; do not swallow.

## Does Canesten® Plus 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 cream for a long period during pregnancy, particularly in the first three months. It is preferable to avoid the use of Canesten® Plus 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 cream.

## Can Canesten® Plus 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 cream exert any effects on the ability to drive and use machines?

Canesten® Plus 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 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