

CÓDIGO Nº.8095542000 - Nº VERSIÓN DE COMPRA: 10 - ANULA A:

FIRMA:
FECHA: 08/05/2012 HORA: 08:45

REF. ESP.: P041
MEDIDAS PERFIL: 148 x 210 mm sin doblar

ESCALA 1:1

Prospecto (anverso)
Canesten Plus HC 1 30g
AU

COLORES REF.

 Negro  Troquel
 p.200



OBSERVACIONES: Tonos de color no válidos para la impresión

 L. Vallespin SA

Consumer Medicine Information



Canesten® Plus

CLOTRIMAZOLE AND HYDROCORTISONE CREAM

CANESTEN Plus Clotrimazole and Hydrocortisone Cream contains 10 mg/g of clotrimazole and 11.2 mg/g of hydrocortisone acetate as active ingredients.

What is in this leaflet?

This leaflet answers some common questions about CANESTEN Plus Clotrimazole and Hydrocortisone Cream. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your pharmacist has weighed the risks of you using CANESTEN Plus Clotrimazole and Hydrocortisone Cream against the benefits they expect it will have for you. If you have any concerns about this medicine, ask your doctor or pharmacist. Keep this leaflet with your medicine. You may need to read it again.

What is CANESTEN Plus Clotrimazole and Hydrocortisone Cream used for?

CANESTEN Plus Clotrimazole and Hydrocortisone Cream is used on the skin to treat and soothe inflamed fungal skin conditions such as:

- Tinea pedis (athlete's foot)
- External symptoms of thrush
- Jock itch
- Fungally infected nappy rash
- Ringworm
- Fungal skin rash
- Fungally infected eczema or dermatitis.

CANESTEN Plus Clotrimazole and Hydrocortisone 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. For conditions without inflammation use an antifungal agent without hydrocortisone, such as Canesten Clotrimazole Antifungal Cream.

This product should only be used in children under 2 years of age (for example, fungal nappy rash) if a doctor has told you to.

Before using CANESTEN Plus Clotrimazole and Hydrocortisone Cream

Do not use CANESTEN Plus Clotrimazole and Hydrocortisone Cream if:

- you have an allergy to any of the ingredients of CANESTEN Plus Clotrimazole and Hydrocortisone Cream listed at the end of this leaflet
- the skin on the area to be treated is cracked or broken
- you have a viral skin infection (such as cold sores, shingles or chicken pox)

- you have other infections of the skin (such as acne, rosacea, perioral dermatitis, lues, tuberculosis)
- you have a reaction of the skin resulting from a vaccination.

Do not use CANESTEN Plus Clotrimazole and Hydrocortisone Cream if the packaging is torn or shows signs of tampering.

Do not use CANESTEN Plus Clotrimazole and Hydrocortisone Cream if the expiry date (EXP) printed on the pack has passed. If you use this medicine after the expiry date has passed, it may not work as well.

Do not use CANESTEN Plus Clotrimazole and Hydrocortisone Cream just before having a bath, shower or going swimming. If you do, you may reduce the effectiveness of CANESTEN Plus Clotrimazole and Hydrocortisone Cream.

Consult your doctor or pharmacist first if:

- you have allergies to any other medicine or any other substances such as foods, preservatives or colours
- you have cuts or abrasions at or near the area to be treated. The chance of unwanted effects may be increased.

Tell your doctor before use if you are pregnant or breastfeeding. Your doctor will discuss with you the risks and benefits of using this product while pregnant or breastfeeding.

Tell your doctor or pharmacist if you are using 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 do I use CANESTEN Plus Clotrimazole and Hydrocortisone Cream?

Follow all directions given to you by your doctor or pharmacist carefully. These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your pharmacist for help.

It is important to use CANESTEN Plus Clotrimazole and Hydrocortisone Cream exactly as your doctor or pharmacist has told you. If you use it less often than you should, it may not work as well and your skin problem may not improve. Using it more often than you should may not improve your skin problem any faster and may cause or increase side effects.

Before use, pierce the seal on the tube by inverting the cap over the end of the tube and pressing.

A small amount of CANESTEN Plus Clotrimazole and Hydrocortisone Cream should be applied thinly and

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evenly with gentle rubbing to the affected area(s) twice daily. Use only until inflammation, itching, and redness have subsided, and not for more than 7 days (unless a doctor has told you to). Then use a clotrimazole-only cream, such as CANESTEN Clotrimazole Anti-fungal Cream for 14 days after symptoms disappear to avoid recurrence of the infection.

If you use too much (overdose)

Telephone your doctor or the Poisons Information Centre (Australia 131 126) or go to the nearest Accident and Emergency department immediately if you think that you or anyone else may have used too much CANESTEN Plus Clotrimazole and Hydrocortisone Cream. Do this even if there are no signs of discomfort or poisoning. You may need medical attention.

While you are using CANESTEN Plus Clotrimazole and Hydrocortisone Cream

Tell your doctor if you become pregnant, are breastfeeding or intend to breastfeed while using CANESTEN Plus Clotrimazole and Hydrocortisone Cream.

In infants, care should be taken not to fasten nappies too tightly over the treated area, as this may increase the chance of side effects.

Do not use CANESTEN Plus Clotrimazole and Hydrocortisone Cream in or near the eyes.

Do not give CANESTEN Plus Clotrimazole and Hydrocortisone Cream to anyone else, even if they have the same symptoms as yours. Do not use CANESTEN Plus Clotrimazole and Hydrocortisone Cream to treat other complaints unless your doctor or pharmacist tells you to.

Do not use CANESTEN Plus Clotrimazole and Hydrocortisone Cream under dressings or on large areas of the skin unless your doctor tells you to.

Do not use large amounts of CANESTEN Plus Clotrimazole and Hydrocortisone Cream for a long time. If you use large amounts for a long time, the chance of absorption through the skin and the chance of side effects increases.

Ask your doctor or pharmacist if you are concerned about the length of time you have been using CANESTEN Plus Clotrimazole and Hydrocortisone Cream.

Are there any unwanted effects when using CANESTEN Plus Clotrimazole and Hydrocortisone Cream?

CANESTEN Plus Clotrimazole and Hydrocortisone Cream helps most people but a few people may experience unwanted effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

After the application of CANESTEN Plus Clotrimazole and Hydrocortisone Cream a slight stinging sensation may occasionally be noticed. This will most likely disappear after several applications.

Skin reactions (such as hypersensitivity reactions e.g. burning, stinging, swelling 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 (air and watertight) dressings, local skin changes may occur.

Ask your doctor or pharmacist to answer any questions you may have.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After Using CANESTEN Plus Clotrimazole and Hydrocortisone Cream

Storage: Store CANESTEN Plus Clotrimazole and Hydrocortisone Cream below 25°C in a cool, dry place. Do not store in the bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep CANESTEN Plus Clotrimazole and Hydrocortisone Cream where young children cannot reach it. A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Do not use after the expiry date printed on the pack.

Disposal: If your doctor tells you to stop using CANESTEN Plus Clotrimazole and Hydrocortisone Cream or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product Description

What it looks like

CANESTEN Plus Clotrimazole and Hydrocortisone Cream is a white to slightly yellowish cream.

Ingredients

CANESTEN Plus Clotrimazole and Hydrocortisone Cream contains 10 mg/g of clotrimazole and 11.2 mg/g of hydrocortisone acetate as the active ingredients. It also contains:

- benzyl alcohol
- cetosteryl alcohol
- tricetareth-4-phosphate
- triglycerides medium-chain
- sodium hydroxide
- water

Sponsor

CANESTEN Plus Clotrimazole and Hydrocortisone Cream is supplied in Australia by:

Bayer Australia Ltd.
875 Pacific Highway, Pymble, NSW 2073
Ph: 1800 023 884

CANESTEN Plus Clotrimazole and Hydrocortisone Cream is supplied in New Zealand by:

Bayer New Zealand Ltd.
3 Argus Place, Hillcrest, Auckland 0627
Ph: 0800 847 874

CANESTEN Plus Clotrimazole and Hydrocortisone Cream is made in Spain.

Date of Preparation: 7 May 2012

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