

ZALAIN CREAM

Sertaconazole Nitrate 2%

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What ZALAIN CREAM is used for?

ZALAIN cream contains Sertaconazole nitrate as the active ingredient.

ZALAIN cream is effective in topical treatment of surface skin mycoses, such as dermatophytosis, Tinea pedis (athlete's foot), Tinea cruris (Hebra's eczema), Tinea corporis (herpes circinatus), Tinea barbae (beard mycosis) and Tinea manus, Candidiasis (moniliasis) and Pityriasis versicolor (Pityrosporum orbiculare, Malassezia furfur formerly).

How ZALAIN CREAM works

Sertaconazole inhibits the growth of pathogenic fungi causing a blockage at the level of ergosterol synthesis that produces the structural and functional change of the fungal cytoplasmic membrane. In addition, the exposure to sertaconazole causes a direct damage on the fungal plasma membrane which implies a fungicidal effect.

Before you use ZALAIN CREAM

When you must not use it

Do not take ZALAIN CREAM:

If you are allergic (hypersensitive) to Sertaconazole Nitrate, or to any of the ingredients.

Before you start to use it

Always tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Do not use Zalaín cream for ophthalmic treatments. Avoid contact with eyes. In case of accidental contact, rinse the eyes with water.

In patients that have been treated for a long period with a topical corticosteroid and in order to avoid a possible appearance of sensitisation induced by corticosteroids, it is recommended to discontinue the treatment two weeks before the use of ZALAIN Cream.

Warnings for excipients

ZALAIN Cream contains sorbic acid as excipient and may cause local skin reactions (as contact dermatitis).

It also contains methyl p-hydroxybenzoate which may cause allergic reactions (possibly delayed).

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use ZALAIN CREAM

How much to use

Apply ZALAIN Cream to the affected areas also covering the adjacent area.

When to use it

Apply ZALAIN cream once or

twice a day (preferably in the evening or morning and evening).

How long to use it

The usual duration of treatment is 3 to 4 weeks.

If there is no clinical recovery after 4 weeks of treatment, the diagnosis should be confirmed. Apply general hygienic measures to control infection and reinfection sources. The posology for children older than 12 years is the same as that recommended for adults.

If you forget to use it

If you use too much (overdose)

As the use is only topical, overdose is not foreseen. However, in case of accidental ingestion, please consult your doctor.

While you are using it

Things you must do

- Use your medicine exactly as your doctor has told you.

Things you must not do

- Do not give ZALAIN Cream to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines
Sertaconazole Nitrate is not expected to affect the ability to drive or use machines.

Side effects

Like all medicines, ZALAIN CREAM can cause side effects, although not everybody gets them.

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Following the topical application of Zalaín® cream, skin disorders as erythema, burning sensation and itching may very rarely appear (<0.01%, that is, isolated cases). After the application of ZALAIN Cream, allergic reactions may possibly appear with the manifestation of itching, erythema or vesicles in the application area or in a scattered way.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website nptra.moh.gov.my [Public Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of ZALAIN CREAM

Storage

Store below 30°C

Keep out of reach of children.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

ZALAIN® cream is a white-coloured semi-solid cream of fluid consistency, odourless or with a faint fatty odour.

Ingredients

Active ingredient

Sertaconazole Nitrate

Inactive ingredients

ethyleneglycol and polyethyleneglycol palmito stearate, lauroyl macrogolglycerides, glyceryl isostearate, light paraffin oil, methyl p-hydroxybenzoate, sorbic acid, purified water, q.s

MAL number(s):

Manufacturer

Ferrer Internacional S.A.,
Joan Buscalla, 1-9
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Product Registration Holder

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