

# MYCOSTER®

Ciclopirox Olamine

1%

## 1 - IDENTIFICATION OF THE MEDICINE. Name:

Mycoster® 1%, solution for cutaneous application.

## Qualitative and quantitative composition:

Each 100 ml Mycoster contains:

Ciclopirox Olamine 1.000 g. Excipients: Macrogol 400, isopropanol, purified water

## Pharmaceutical forms:

Solution for cutaneous application, 15 ml bottle.

## Pharmaco-therapeutic class:

ANTIFUNGAL FOR TOPICAL USE (Dermatological medicine).

## 2- Therapeutic indications:

Dermatoses, whether or not superinfected by bacteria. Dermatophyte fungal nail infections, mild to moderate seborrhoeic dermatitis of the face.

## 3- Contraindications:

This medicine **SHOULD NOT BE USED** in the event of allergy to one of the product's Ingredients. **IF DOUBT, ASK YOUR DOCTOR OR PHARMACIST'S ADVICE.**

## Special warnings:

Do not apply this medicine near the eyes. Do not swallow. Inform your doctor if you are pregnant.

## Precautions for use:

Do not apply this medicine in the ocular area. Candidiasis: it is not recommended to use a pH acid soap (pH favourable to development of candida). **IF DOUBT, ASK YOUR DOCTOR OR PHARMACIST'S ADVICE.**

## Drug interactions and other interactions:

**IN ORDER TO PREVENT POSSIBLE INTERACTIONS BETWEEN SEVERAL MEDICINES, YOU MUST SYSTEMATICALLY INFORM YOUR DOCTOR OR PHARMACIST IF YOU ARE TAKING ANY OTHER MEDICINES.**

## Pregnancy - Breast-feeding:

**IN GENERAL, IF YOU ARE PREGNANT OR BREAST-FEEDING, YOU SHOULD ALWAYS ASK YOUR DOCTOR OR PHARMACIST BEFORE TAKING ANY MEDICINE.**

## 4 - METHOD OF APPLICATION:

Fungal skin infections: 2 daily applications, for an average of 21 days.

Dermatophyte fungal nail infections: apply Mycoster® 1% solution alone or in association with another treatment for several months.

Mild to moderate seborrhoeic dermatitis of the face: 2 applications per day over 2 to 4 weeks then 1 application per day for 28 days.

## Method and route of administration:

Cutaneous route. For external use only.

## Treatment duration:

Respect your doctor's advice.

## 5 - Adverse effects:

**LIKE ANY ACTIVE SUBSTANCE, THIS MEDICINE MAY CAUSE MORE OR LESS UNPLEASANT EFFECTS IN CERTAIN PEOPLE: -**

During initial applications, local signs (burning sensation, redness, pruritus) may become worse in certain cases; these phenomena are temporary: do not stop treatment - In very exceptional cases, local reactions may persist: stop treatment and consult your doctor **REPORT ANY UNDESIRABLE OR UNPLEASANT EFFECT NOT MENTIONED IN THIS LEAFLET TO YOUR DOCTOR OR PHARMACIST.**

## 6 - STORAGE: Do not exceed the expiry date indicated on the external packaging Special precautions for storage:

This medicine must be stored at a temperature below 30 °C.

Authorized medicines N° in France: 330 411-4 (solution for cutaneous application).



Pierre Fabre

Manufactured by:

**GLOBAL NAPI PHARMACEUTICALS**

6<sup>th</sup> of October City - Giza - EGYPT

Under license of **Pierre Fabre Médicament-France**