PATIENT INFORMATION LEAFLET

BUTEFIN 1% cream

For external use only.

.Active substance: Each 1 gram cream contains 10 mg butenafine hydrochloride.

.Excipients: Benzyl alcohol, sorbitan monostearate, cetyl palmitate 95, zinc oxide, sodium hydroxide, cetyl alcohol, stearyl alcohol, polysorbate 60, isopropyl myristate, and deionized water.

Read this PATIENT INFORMATION LEAFLET carefully before you start using this medicine, because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower** doses than the dose which was recommended for you.*

What is in this leaflet:

1. What BUTEFIN is and what is it used for?

- BUTEFIN is a Butenafine hydrochloride containing cream which is only externally used. It is presented in 15 g and 30 g aluminum tubes.

- BUTEFIN is used for the topical treatment of yellowish brown or brown rash (tinea versicolor) that form on the skin due to a kind of fungus, body fungus (tinea corporis), athlete's foot (interdigital tinea pedis) and crotch itch (tinea cruris).

2. What you need to know before you use BUTEFIN?

Do NOT use BUTEFIN:

- if you are allergic to butenafine hydrochloride and any component of BUTEFIN
- if you are using another topical cream concurrently
- for children under 12 years of age

Use BUTEFIN with CAUTION in the following cases:

Avoid contact of BUTEFIN with mucous membranes such as eyes, nose, mouth.

If skin irritation develops, discontinue using the cream.

Use BUTEFIN with caution if you are allergic to allylamine group antifungal agents (e.g.: terbinafine).

If you are sensitive to fungicides (allylamine group antifungal agents, eg terbinafine), use BUTEFIN carefully.

If you are pregnant, do not use the cream without consulting to a doctor.

If these warnings are valid for you even for any period in the past, please consult your doctor.

BUTEFIN with food and drink:

It has no interaction with food and drinks.

Pregnancy:

Consult your doctor or pharmacist before using this medicine.

Use during pregnancy only if clearly needed and under the supervision of your doctor.

If you realize that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breastfeeding:

Consult your doctor or pharmacist before using this medicine.

Since BUTEFIN may be excreted in breastmilk, do not use during lactation without consulting your doctor.

Effects on ability do drive and use of machines:

It has no effect on ability to drive and use of machines.

Important information about some excipients contained in BUTEFIN:

It may cause delayed type allergic reactions or local skin reactions due to the excipients present in its content.

Since BUTEFIN contains cetyl alcohol and stearyl alcohol, it may cause local skin reactions (e.g., contact dermatitis) or irritation of eyes and mucous membranes.

Usage with other medicines

There is not known or expected interaction between BUTEFIN and other medicinal products through topical administration.

If you are currently using or recently used a prescribed or non-prescribed medicine, please inform your doctor or pharmacist about it.

3. How to use BUTEFIN?

- **Instructions for appropriate use and dosage/frequency:**

Unless otherwise instructed by a doctor; use BUTEFIN as follows:

-In the treatment of athlete's foot, apply twice daily for 7 days or once daily for 4 weeks.

-In the treatment of body fungus or crotch itch, apply once daily for 2 weeks.

- **Way and method of administration:**

BUTEFIN is for external use only.

Apply over the skin covering the affected area and its close surrounding. Wash your hands after use.

- **Different age groups:**

Pediatric use:

It should not be used for children under 12 years of age.

Geriatric use:

Use in elderly people is the same as in adults.

- **Special conditions for use**

Kidney/liver failure:

No specific instructions for use are present for patients with severe renal or hepatic failure.

If you feel that the effect of BUTEFIN is too weak or too strong, talk to your doctor or pharmacist.

If you have used BUTEFIN more than you should:

If you have used BUTEFIN more than you should, inform your doctor or pharmacist.

Since BUTEFIN is used on a limited and superficial area, it has no adverse effect related with its overdose.

If you forget to use BUTEFIN:

Do not use a double dose to make up for the missed dose.

Effects that may occur when treatment with BUTEFIN is discontinued:

None. If no improvement is observed after the treatment period, the diagnosis and therapy should be reviewed.

4. Possible side effects

As it is for all medicines, side effects can be seen in people who are sensitive to the ingredients of BUTEFIN.

Side effects were listed as shown in the following categories:
Very common: may be seen at least 1 in 10 patients.
Common: may be seen less than 1 in 10 patients but 1 in 100 patients or more than 1.
Uncommon: may be seen less than 1 in 100 patients but more than 1 in 1.000 patients or more than 1.
Rare: may be seen less than 1 in 1.000 patients but more than 1 in 10.000 patients or more than 1.
Very rare: may be seen less than 1 in 10.000 patients.
Unknown: it cannot be estimated from the available data.

If you experience any of the following, stop using BUTEFIN and IMMEDIATELY consult your doctor or apply to the emergency service of the nearest hospital.

- Swelling of the face, tongue and throat
- Shortness of breath, wheezing

All of these are very serious side effects.

If you have any one of these side effects, then it indicates that you have serious allergy to BUTEFIN. You may require medical intervention or you should be hospitalized.

All these very serious side effects are observed very rarely.

Consult your doctor if you realize any of the following:

Common

- Itching
- Redness, irritation
- Burning/stinging
- Skin lesions (contact dermatitis)

If you experience any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store BUTEFIN?

Keep BUTEFIN in its package, out of sight and reach of children.

Keep at room temperature below 25°C.

Use in accordance with its expiry date.

Use BUTEFIN before the expiry date indicated on the tube or the package.

Do not use BUTEFIN if you notice any defect in the product and/or its packaging.

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