PATIENT INFORMATION LEAFLET

BUTEFIN 1% Cream
For topical use.

Active substance(s): Each 1 gram cream contains 10 mg butenafine hydrochloride.
Excipient(s): 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 it is used for?

BUTEFIN is a butenafine hydrochloride-containing cream which is only topically 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 –Before you use BUTEFIN

Do not use BUTEFIN in the following conditions:

- if you are allergic (hypersensitive) to butenafine hydrochloride and any of the other ingredients of BUTEFIN,
- if you are using another topical cream concurrently,
- for children under 12 years of age

TAKE SPECIAL CARE WITH BUTEFIN in the following conditions:
Avoid contact of BUTEFIN with eyes, nose, mouth or mucous membranes.

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

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Using BUTEFIN with food and drink:
It has no interaction with food and drinks.

Pregnancy:
Ask your doctor or pharmacist for advice before taking the medicine.
Use during pregnancy only when necessary and under the supervision of your doctor.
If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.

Breastfeeding:
Ask your doctor or pharmacist for advice before taking the medicine
Since BUTEFIN passes into breast milk, do not use during lactation without consulting your doctor.

Effects on ability to drive and use machines:
It has no known effect on ability to drive and use machines.

Important information about some of the excipients of 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.

Using with other medicines
There is no known or expected interaction between BUTEFIN and other medicinal products through topical administration.

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.

3 – How to use BUTEFIN?
Instructions for appropriate method and dose/frequency of administration:
Unless otherwise recommended 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.

Route and method of administration:
BUTEFIN is only for topical use.
- Apply over the skin covering the affected area and its close surrounding. Wash your hands after use.

Different age groups:
Use in children:
It should not be used for children under 12 years of age.

Use in elderly:
Use in elderly patients is the same as in adults.

Special populations:
Kidney/Liver failure:
There is no special use for patients with severe kidney or liver failure.
If you have the impression that the effect of BUTEFIN is too strong or too weak, talk to your doctor or pharmacist.

If you have used more BUTEFIN than you should:
If you may have taken more BUTEFIN than you should, talk to a doctor or pharmacist.
Since BUTEFIN is applied on a limited and superficial area, it has no adverse effect related with overdose.

If you forget to use BUTEFIN:
Do not use a double dose to make up for a forgotten dose.

If you stop using BUTEFIN:
None. If no improvement is observed after the treatment period, the diagnosis and therapy should be reviewed.

4- Possible side effects
Like all medicines, side effects can occur in people sensitive to the contents of BUTEFIN.

If any of the following occur stop using BUTEFIN and IMMEDIATELY inform your doctor or go to the nearest emergency department
- Swelling of the face, tongue and throat,
- Shortness of breath, wheezing

These are all very serious side effects. If you have any of them, this means you have serious allergy to BUTEFIN. You may need emergency medical care or hospitalization.

These very serious side effects occur very rarely.

If you notice any of the following, inform your doctor:
- Itching
- Redness, irritation
- Burning/stinging
- Skin lesions (contact dermatitis)

If you notice any side effects not mentioned in this leaflet inform your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via clicking "Reporting of Drug Side Effects" icon on the website www.titck.gov.tr or Turkish Pharmacovigilance Center (TUFAM) by calling the phone number 0 800 314 00 08 for side effects reporting line. By reporting side effects, you can help provide more information on the safety of this medicine.

5- How to store BUTEFIN?
Keep in the original package and out of the reach and sight of children.
Store in room temperature under 25°C.

Use in accordance with expiry date.
Do not use BUTEFIN after the expiry date which is stated on the tube or package.
Do not use BUTEFIN if you notice any damage to the product and/or package.

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