PATIENT INFORMATION LEAFLET

BUTEFİN 1% topical spray, solution
For external application on the skin.

- ***Active substance(s):*** Each 1 ml solution contains 10 mg butenafine hydrochloride.
- ***Excipient(s):*** Propylene glycol, diethylene glycol monoethyl ether, methyl paraben (E218), propyl paraben (E216) and purified water.

Read all of this 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, 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 BUTEFİN is and what it is used for?

- BUTEFİN is marketed in packages containing 15 ml and 30 ml solution in amber colored glass bottles (Type III) with PE capillary tube and PP spray cap immersed in the bottle, which is the primary packaging material. It contains Butenafine hydrochloride as an active ingredient and is an external solution only.

- BUTEFİN is used in the topical treatment of yellowish brown or brown rashes caused by a type of fungus on the skin (tinea versicolor), body fungus (tinea corporis), inguinal fungus (tinea cruris).

2. What you need to know before you use BUTEFİN*
Do not use BUTEFİN
If;

- If you are allergic to butenafine hydrochloride and other ingredients of this medicine,
- If you are using any other topical medication at the same time,
- In children under 12 years of age.

Warnings and precautions
Avoid contact of BUTEFİN with eyes, nose, mouth or mucous membranes.

If skin irritation occurs, discontinue use.

If you are sensitive to allylamine group antifungal agents (fungicides, eg terbinafine), use BUTEFİN with caution.

Do not use in case of pregnancy without consulting a doctor.

If these warnings apply to you, even if at any time in the past, please consult your doctor.

BUTEFİN with food and drink
No interaction with food and drink.

Pregnancy
Consult your doctor or pharmacist before taking this medicine.
Use during pregnancy only when necessary and under the control of your doctor.
Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

Breastfeeding
Consult your doctor or pharmacist before taking this medicine.
Since BUTEFİN can pass into breast milk, do not use it during breastfeeding without consulting your doctor.

Driving and using machines
It has no known adverse effects on the use of machines and driving.

Important information about excipients in BUTEFİN
Propylene glycol in its content may cause skin irritation.

Methyl paraben and propyl paraben in its content may cause allergic reactions (possibly delayed).

Other medicines and BUTEFİN
There are no known or expected interactions of BUTEFİN with other medicinal products via topical application.

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to use BUTEFİN?
- **Instructions for use and dosage/frequency of administration:**

BUTEFİN is used as follows, unless recommended otherwise by the doctor;

- For body fungus or inguinal fungus, apply once a day for 2 weeks.

- **Route of administration and method:**

BUTEFİN is for external use only. It is suitable for use on hairy body areas.
Apply on the skin to cover the affected area and its immediate surroundings. Wash your hands after applying the medicine.

- **Different age groups:**

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

Use in elderly:
The use of BUTEFİN in elderly patients is the same as in adults.

- **Special cases of use:**

Renal/Hepatic failure:
There is no specific use in case of severe kidney and liver failure.

If you have impression that the effect of BUTEFİN is very strong or weak, tell a doctor or pharmacist.

If you use more BUTEFİN than you should:
If you take more BUTEFİN than you should, tell your doctor or pharmacist.

Since BUTEFİN is used in a limited and superficial area, overdose has no side effects.

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

If you stop using BUTEFİN:
Not available. If no improvement is seen after the treatment period, the diagnosis and treatment should be reviewed.

4. Possible side effects?
Like all medicines, BUTEFİN can cause side effects, although not everybody gets them.

If you notice any of the followings stop taking BUTEFİN and immediately inform your doctor or go to the nearest emergency department:

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

These are very serious side effects. If you have these side effects, it means you have a serious allergy to BUTEFİN. You may need emergency medical attention or hospitalization.

All of these very serious side effects are very rare.

If you notice any of the followings, inform your doctor:

- Itching
- Redness, irritation on the skin
- Burning/stinging
- Skin ulcer (contact dermatitis)

These are mild side effects of BUTEFİN.

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

5. How to store BUTEFİN?
Keep this medicine out of the sight and reach of children, in the original package.
Store at room temperature below 25°C.

Use in accordance with expiry date.
Do not use BUTEFİN after the expiry date which is stated on the package.

Do not use BUTEFİN if you notice any damage to the product and/or package.

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