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PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS), 1986

This medicine is dispensed without a doctor's prescription

BIFOVIT, Cream

Composition: Bifonazole 1%

For the list of inactive ingredients in the preparation, see section 6-"Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

Take the medicine properly. Consult a pharmacist if you need further information. Refer to a doctor if the disease symptoms worsen or do not improve.

This medicine has been prescribed for the treatment of your ailment. Do not give this medicine to other people. It might harm them even if it looks to you that their medical situation is similar.

1. What is the medicine intended for?

Broad spectrum antifungal product, for the treatment of fungal infections of the skin.

Therapeutic Group: Imidazole class antifungal drug

2. Before using the medicine:

Do not use this medicine if: you have a known sensitivity to the active Ingredient or to any of the other ingredients of the medicine

Special warnings regarding use of the medicine:

- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- Avoid contact with the eyes. In case of contact, wash the eyes with water immediately.
- If you are taking another drug concomitantly or if you have just finished treatment with **other medicines**, including non prescription drugs and dietary supplements, inform the attending doctor, or the pharmacist, in order to prevent hazards or lack of efficacy arising from drug interactions.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, do not use this medicine without consulting a doctor prior to starting treatment.

Important information about some of the ingredients of the medicine:

The medicine contains Benzyl Alcohol 1% as a preservative.

3. How should you use the medicine?

Always use according to doctor's instructions.

You should check with your doctor or pharmacist if you are not sure.

The dosage and the way of treatment will be set by the doctor only.

The usual dosage is: apply on the affected area once daily, preferably at bedtime.

Do not exceed the recommended dose!

Attention: Do not swallow! This medicine is intended for external use only!

Avoid contact of this medicine with the eyes or mucus membranes (such as mouth and nose).

- **If you took an overdose or if a child accidentally swallowed this medicine,** proceed immediately to a hospital emergency room and bring the package of the medicine with you.
- **Do not induce vomiting** unless explicitly instructed to do so by a doctor!

How can you contribute to the success of the treatment?

Complete the full course of treatment as instructed by the doctor. Even if there is an improvement in your health, do not discontinue use of this medicine, before consulting your doctor.

Moisture enhances fungal growth. Therefore the affected area should be kept dry.

- **Directions for use:** Wash and dry the affected area. Apply a thin layer and rub gently into the skin. Between each application of the product - talcum powder may be used in order to keep the area dry.

- If feet are treated – ensure thorough washing and drying especially between the toes. It is advisable to wear cotton socks. Avoid wearing woolen or synthetic socks. It is advisable to change socks several times a day (depending on the amount of sweat). In appropriate seasons, it is recommended to wear sandals without socks.
- **Do not take medicines in the dark!** Check the label and the dose each time you take your medicine. Wear glasses if you need them.
- If you have further questions concerning the use of this medicine, consult a doctor or a pharmacist.

4. Side Effects

As with any medicine, use of Bifovit may cause side effects, in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Side effects might occur as follows:

- Light redness, itching or a burning feeling of the skin. These effects are rare, and usually disappear after a short time of adaptation to the medicine.
- **Effects that require special attention:** Prolonged itching, local rash or inflammation (which were not present before starting treatment with this medicine), nausea, dizziness (rare): stop treatment and refer to your doctor.
- In the event that you experience side effect, or if a side effect worsen, if you suffer a side effect not mentioned in this leaflet, consult your doctor .
- Adverse reactions and drug interactions in **children and infants**: Parents must inform the attending doctor about any side effect, as well as any additional medicine being taken by the child.

Side effects may be reported to the Ministry of Health by clicking the link "Report of side effects due to medication" on the home page of the Ministry of Health website (www.health.gov.il), which will open an online form for reporting side effects.

5. How should the medicine be stored?

- Store at a temperature below 25°C
- Do not use the medicine after the expiry date (Exp. Date) shown on the package. The expiry date refers to the last day of that month.
- Can be used for up to 6 months after opening the tube for the first time, but not beyond the medicine's expiry date appearing on the packaging.
- The medicine is a semi transparent, white to cream coloured cream. Do not use the medicine if you observe any change in the medicine's texture or colour which might be a sign to decomposition of the medicine.
- Store in the original container only. Do not store different medicines in the same package.
- **avoid poisoning!** This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning.

6. Further information

In addition to the active ingredient, the medicine also contains the following inactive ingredients:

Purified Water, Octyldodecanol, Cetostearyl Alcohol, Cetyl Palmitate, Sorbitan Monostearate, Polysorbate 60, Benzyl Alcohol.

What does the medicine look like and what are the contents of the package:

The medicine is a semi-transparent white to off-white cream, packed in a 15 gram tube.

Manufacturer and license holder:

Vitamed Pharmaceutical Industries Ltd.

P.O.B 114, Binyamina 3055002, Israel.

This leaflet was checked and approved by the Ministry of Health in 07/2014

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