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

The medicine is dispensed without a doctor's prescription

BIAFINE, cream for skin application

Active ingredient

Triethanolamine (Trolamine) 0.670 g/ 100 g

Inactive and allergenic ingredients: see section 6 *"Further Information"* and section 2 "*Before using the medicine*".

Read the 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.

Use this medicine in accordance with the instructions in the dosage section in this leaflet. Consult the pharmacist if you need further information. Refer to the doctor if signs of the illness worsen or do not improve.

1. WHAT IS THE MEDICINE INTENDED FOR?

Soothes burns, sunburns, sores and wounds.

Therapeutic group: SKIN PROTECTOR (D. Dermatology).

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- **You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see details in section 6 – "Further Information").**
- You have a haemorrhagic wound (with bleeding).
- You have an infected wound.

IN CASE OF DOUBT, IT IS ESSENTIAL TO ASK YOUR DOCTOR OR PHARMACIST FOR THEIR OPINION.

Special warnings regarding use of the medicine

Talk to your doctor or pharmacist before using BIAFINE, cream for skin application.

If you have a burn with blistering or extensive burn, or if you have a deep or extensive wound, medical consultation is essential before applying any medicine to the wound.

This medicine does not provide protection from the sun.

This medicine should not be used as a skincare cream for healthy skin.

Do not apply near the eyes.

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR THEIR OPINION.

Children

Not applicable.

Interactions/reactions between other medicines and BIAFINE, cream for skin application

! If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

BIAFINE, cream for skin application with food and drink

Not applicable.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Not applicable.

Important information about some of the ingredients of the medicine

BIAFINE, cream for skin application contains propylene glycol, sodium methyl parahydroxybenzoate (E 219), sodium propyl parahydroxybenzoate (E 217) and Yerbatone aroma.

This medicine contains 38 mg of propylene glycol per 1.65 g dose and may cause skin irritation.

Do not use this medicine on babies less than 4 weeks old with open sores or large areas of broken or damaged skin (burns) without first informing your doctor or pharmacist.

This medicine contains potassium sorbate and may cause local skin reactions (e.g. contact dermatitis).

This medicine contains sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate and may cause allergic reactions (possibly delayed).

This medicine contains a fragrance (Yerbatone aroma) containing the following substances: Essential oils (deterpened orange, galbanum, deterpened petitgrain, lemongrass), alcohols, aldehydes, esthers, ketones. These substances can cause allergic reactions.

3. HOW SHOULD THE MEDICINE BE USED?

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the product.

Posology

- **In case of burns**:

  Apply a one-half centimeter layer of Biafine on and around the affected area.

  Reapply the cream regularly in order to maintain a fixed amount on the affected area.

  Note: In case of burns – Cool immediately with cold running water on the burn for 10 minutes, then apply a thick layer of the cream. In case of deep or extensive burns – medical treatment needs to be received.

- **Skin wounds**:

  Generally, a thick layer should be applied on and around the wound without rubbing. Maintain a thick layer until the wound forms a scab. A physician may recommend a suitable dressing.

- **Secondary reactions after radiation therapy (erythema, dry or moist desquamation, "hardening of the skin", etc., with or without pain):**

  Do not apply Biafine 3-4 hours prior to a radiation session.

  Apply Biafine immediately following the first radiation session.

- **When the skin is not damaged:**

  If there are no medical instructions – apply Biafine three times a day.

- **When the skin is cracked (moist desquamation), non-infected wounds:**

  Apply Biafine according to the instructions for treating wounds. If the wound is large, disinfect it before applying Biafine. A physician may recommend a suitable dressing.

  Note:
  Sometimes three applications a day are not sufficient. In such cases, the doctor may recommend an additional two applications a day, one after you wake up in the morning, if you do not have a session that morning (if you do have a session scheduled for that same day, do not apply Biafine),

and another at night before bedtime.

How to use Biafine

- Apply to skin.

Use in children

Not applicable.

If you have used more BIAFINE, a cream for skin application than you should

Not applicable.

If you forget to use BIAFINE, cream for skin application

Not applicable.

If you stop using BIAFINE, cream for skin application

Not applicable.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Biafine 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.

- Moderate and temporary (15-30 minutes) pain (tingling) may occur after application.
- Rare contact allergy.
- Very rare case of contact eczema requiring immediate discontinuation of treatment.
- The presence of certain excipients may possibly cause skin irritation, or local skin reactions (e.g. contact dermatitis) or allergic reactions (possibly delayed).

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Store below 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
  Ethylene glycol monopalmitostearate, stearic acid, cetyl palmitate, hard paraffin, liquid paraffin, perhydrosqualene, propylene glycol*, avocado oil, sodium trolamine alginate, potassium sorbate*, sodium methyl parahydroxybenzoate* (E 219), sodium propyl parahydroxybenzoate* (E 217), yerbatone aroma*, purified water.

* See Section 2

- What the medicine looks like and the contents of the package:

This medicine is in the form of a cream for skin application. 46.5 g, 93 g, or 186 g tubes.

Registration holder:
J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Manufacturer:
Janssen Cilag S.A., Val de Reuil, France

Revised in May 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
067-13-28323