SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

BIAFINE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Trolamine - 0.67% w/w

Excipient(s) with known effect: propylene glycol, potassium sorbate, sodium methyl parahydroxybenzoate (E 219), sodium propyl parahydroxybenzoate (E 217), Yerbatone aroma.

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Cream for skin application.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Soothes burns, sunburns, sores and wounds.

4.2. Posology and method of administration

- **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.

4.3. Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in Section 6.1.
- Haemorrhagic wound.
- Infected wound.
- Do not use this medicine on babies less than 4 weeks old with open sores or large areas of broken

or damaged skin (burns).

4.4. Special warnings and precautions for use

Special warnings

In the event of a second-degree burn or an uninfected skin wound, the action to be taken depends on the extent of the wound, its location, the age and medical history of the patient, related wounds and aetiology.

Precautions for use

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.

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).

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

This medicine contains sodium methyl parahydroxybenzoate (E 219) and sodium propyl parahydroxybenzoate (E 217) 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.

4.5. Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6. Fertility, pregnancy and lactation

Pregnancy

There is no data for pregnant women. However, no effects in pregnant women or in the foetus are expected.

Breast-feeding

There is no data for breast-feeding women. However, no effects in breast-feeding women or infants being breastfed are expected.

There is no data for the transfer of trolamine or its metabolites in breast milk.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

Undesirable effects are categorised according to how often they occur, as follows: uncommon (≥1/1000, <1/100), rare (≥1/10,000, <1/1000) and very rare (<1/10,000).

General disorders and administration site abnormalities:

- Uncommon: moderate and temporary tingling-type pain after application.
- Rare: contact allergy.
- Very rare: contact eczema requiring immediate discontinuation of treatment.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medical product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

https://sideeffects.health.gov.il/

4.9. Overdose

No symptoms of overdosage have been identified from the analysis of post-marketing data and scientific literature for the topical dosage form of this product.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: SKIN PROTECTOR, code ATC: D03AX12 (D. Dermatology).

Mechanism of action

Trolamine, together with fatty acids like stearic acid, acts as an emulsifier. After being applied to the skin, it develops occlusive and moisturising properties, increases the induction of macrophages in the wound, promotes healing in the dermis and the formation of granulation tissue.

5.2. Pharmacokinetic properties

The effects of this medicine are limited to the superficial layers of the epidermis and promote hydration. No systemic effect is expected.

5.3. Preclinical safety data

In vitro mutagenicity and chromosomal aberration tests conducted with trolamine were negative.

The results of carcinogenicity studies in rodents are equivocal. There is no data for humans.

Trolamine has been shown to be embryotoxic in a reproduction study in chickens. There is no data for humans.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Ethylene glycol monopalmitostearate, stearic acid, cetyl palmitate, hard paraffin, liquid paraffin, perhydrosqualene (squalene), propylene glycol, avocado oil, sodium trolamine alginate, potassium sorbate, sodium methyl parahydroxybenzoate (E 219), sodium propyl parahydroxybenzoate (E 217), Yerbatone* aroma, purified water.

*Composition of Yerbatone aroma: Essential oils (deterpened orange, galbanum, deterpened petitgrain, lemongrass), alcohols, aldehydes, esthers, ketones.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4. Special precautions for storage

Store below 25°C.

6.5. Nature and contents of the outer packaging

46.5 g, 93 g, and 186 g aluminium tube, internally coated with epoxyphenolic varnish and sealed with a high density polyethylene stopper.

Not all presentations may be marketed.

6.6. Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. REGISTRATION HOLDER

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

8. MANUFACTURER

JNTL Consumer Health (France) SAS, Val de Reuil, France

9. REGISTRATION NUMBER

067-13-28323.

Revised in March 2024.