BIAFINE® EMULSION FOR CUTANEOUS APPLICATION

IDENTIFICATION OF THE MEDICINAL PRODUCT

TRADE NAME: BIAFINE®, emulsion for cutaneous application.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Per 100 g: Trolamine 0.670 g. Excipients: glycol ethylene stearate, stearic acid, cetyl palmitate, solid paraffin, trolamine and sodium alginate, avocado oil, liquid paraffin, perhydrosqualene, propylene glycol, sodium methyl parahydroxybenzoate (E 219), sodium propyl parahydroxybenzoate (E 217), sorbic acid, fragrance yerbatone, purified water.

PHARMACEUTICAL FORM: Emulsion for cutaneous application. Tube containing 93 g or 186 g.

PHARMACO-THERAPEUTIC CLASS: A cutaneous protective agent (D: dermatology).

NAME AND ADDRESS OF MANUFACTURER: LABORATOIRE MEDIX, 18 rue Saint Mathieu, 78550 Houdan FRANCE - Tel. 01.30.88.16.00.

IN WHICH CASES THIS MEDICATION SHOULD BE USED

- Secondary Erythema due to radiotherapy treatments
- First and second degree burns and all other non-infected cutaneous wounds.

WARNINGS!

IN WHICH CASES THIS MEDICATION SHOULD NOT BE USED

This medication SHOULD NOT BE USED in the following cases:
- Known allergy to one of the ingredients in the formulation.
- Bleeding wounds (with bleeding).
- Infected wounds.

IN CASE OF DOUBT, IT IS ESSENTIAL THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

SPECIAL WARNING

In case of burns with formation of a blister or extensive burns, or in case of a deep or extensive wound, it is **essential** that you **consult your doctor** before applying any medication on the lesion.

PRECAUTIONS FOR USE

This medication does not provide sun protection.

IN CASE OF DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

DRUG INTERACTIONS AND OTHER INTERACTIONS

TO AVOID ANY INTERACTIONS BETWEEN SEVERAL MEDICATIONS, YOU SHOULD SYSTEMATICALLY INDICATE TO YOUR DOCTOR OR PHARMACIST OF ANY OTHER MEDICATION YOU ARE CURRENTLY TAKING.

PREGNANCY AND BREAST-FEEDING

GENERALLY SPEAKING, DURING PREGNANCY OR BREAST-FEEDING, YOU SHOULD ALWAYS ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE BEFORE USING ANY MEDICATION.

LIST OF EXCIPIENTS WHOSE KNOWLEDGE IS NECESSARY FOR RISK-FREE USE IN SOME PATIENTS.

Propylene glycol, potassium sorbate, sodium methyl parahydroxybenzoate (E 219), sodium propyl parahydroxybenzoate (E 217).

HOW TO USE THIS MEDICATION

POSOLOGY

- SECONDARY ERYTHEMA DUE TO RADIOTHERAPY TREATMENTS

Follow your doctor's recommendations.
Generally, 2 to 3 applications a day, at regular intervals, allowing the emulsion to penetrate by gently massaging.

- SECOND DEGREE BURNS AND OTHER CUTANEOUS WOUNDS

A consultation with your doctor is necessary (see warnings).
After cleaning the wound, apply a thick layer of emulsion widely overlapping the surface of the lesion and repeat applications to maintain an excess of emulsion on the lesion.
If necessary, cover with a moistened compress and finish the dressing. Do not use a dry absorbent dressing.

- FIRST DEGREE BURNS

Apply a thick layer until emulsion is no longer absorbed. Allow to penetrate by gently massaging. Repeat 2 to 4 times a day.
In case of an extensive burn, it is essential that you consult your doctor (see warnings).

METHOD AND ROUTE OF ADMINISTRATION

Cutaneous route

UNDESIRABLE AND UNCOMFORTABLE EFFECTS

As with all active product, this medication can, in some persons, cause more or less uncomfortable effects, such as:
- moderate and transient (15 to 30 minutes) pains (stinging) which can occur after application.
- contact allergy, in rare cases.

DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE AND REPORT ANY UNDESIRABLE AND UNCOMFORTABLE EFFECT NOT MENTIONED IN THIS PRODUCT LEAFLET.

STORAGE

- **Do not exceed the expiry date for use clearly marked on the outer package.**
- **Particular precautions for storage:** do not store at temperatures below 0°C.

DATE OF REVISION : January 1997.