

# **BIAFINE**<sup>®</sup>

**T O P I C A L E M U L S I O N**



## **Description**

BIAFINE<sup>®</sup> Topical Emulsion is a water-based emulsion formulated for the dressing and management of superficial wounds, minor abrasions, dermal ulcers, donor sites, 1st and 2nd degree burns, including sunburns, and radiation dermatitis. When applied properly to a wound, BIAFINE<sup>®</sup> Topical Emulsion provides an optimum moist environment for the healing process and isolates the wound from harmful germs and other external contamination.

## **Indications and Usage**

BIAFINE<sup>®</sup> Topical Emulsion is indicated for use in:

- Full Thickness Wounds, Pressure Sores, Dermal Ulcers including Lower Leg Ulcers
- Superficial Wounds
- 1st and 2nd Degree Burns, including Sunburns
- Dermal Donor and Graft Site Management
- Radiation Dermatitis
- Minor Abrasions

## **Contraindications**

BIAFINE<sup>®</sup> Topical Emulsion is contraindicated for use on bleeding wounds, skin rashes related to food or medicine allergies, and when an allergy to one of the ingredients is known.

## **Warnings**

- In radiation therapy, BIAFINE<sup>®</sup> Topical Emulsion may be applied as directed by the treating physician. Do not apply 4 hours prior to a radiation session.
- Do not apply BIAFINE<sup>®</sup> Topical Emulsion to dermal grafts until after the graft has successfully taken.
- Keep out of the reach of children.

## **Precautions and Observations**

- For the treatment of any dermal wound, consult a physician. Use BIAFINE<sup>®</sup> Topical Emulsion only as directed.
- BIAFINE<sup>®</sup> Topical Emulsion is non-toxic, it is for topical use only, and should not be ingested or taken internally. If ingested or taken internally, contact a doctor or Poison Control Center immediately.
- BIAFINE<sup>®</sup> Topical Emulsion does not contain a sunscreen and should not be used prior to extended exposure to the sun.
- The use of BIAFINE<sup>®</sup> Topical Emulsion on skin rashes due to allergies has not been studied sufficiently and therefore is not recommended.
- Following the application of BIAFINE<sup>®</sup> Topical Emulsion a temporary tingling sensation may occur (10 to 15 minutes).
- If clinical signs of infection are present, appropriate treatment should be initiated. If clinically indicated, use of BIAFINE<sup>®</sup> Topical Emulsion may be continued during the anti-infective therapy.
- If condition does not improve within 10-14 days, consult a physician.
- BIAFINE<sup>®</sup> Topical Emulsion may dissolve fuchsin when this dye is used to define the margins of the radiation fields to be treated.

## **Instructions for Use**

BIAFINE<sup>®</sup> Topical Emulsion is for topical use only as directed by a healthcare professional.

### **Wounds, Abrasions, Full Thickness Wounds, Dermal Graft Site Management and Donor Site Management**

- Wash the affected area(s) with saline, clean water, or a suitable wound cleanser.
- Apply BIAFINE<sup>®</sup> Topical Emulsion on and around the affected area(s) in thick layers 1/4 to 1/2 inch thick.
- If applying gauze dressing, moisten the dressing lightly before application.
- Reapply BIAFINE<sup>®</sup> Topical Emulsion as described above every 24 to 48 hours or as directed until the wound or lesion has healed fully.
- For donor site management, apply BIAFINE<sup>®</sup> Topical Emulsion after skin removal and cover with a moist dressing. Reapply as directed.
- For dermal graft site management, apply BIAFINE<sup>®</sup> Topical Emulsion to the graft site only after the graft has taken successfully. BIAFINE<sup>®</sup> Topical Emulsion can be washed away with a saline solution or clean water without causing damage to the newly formed tissues.

### **1st and 2nd Degree Burns, Including Sunburns**

- Before application of BIAFINE® Topical Emulsion to burns, take precaution in removing any clothing in the affected area(s).
- Apply BIAFINE® Topical Emulsion as soon as possible on and around the affected area(s), in a thick 1/4 to 1/2 inch layer until the skin no longer absorbs the product. A white waxy residue may remain. If pain from the burn persists, apply thinner layers of BIAFINE® Topical Emulsion until the pain has ceased.
- Continue to apply BIAFINE® Topical Emulsion until the affected area(s) has healed completely.
- Application of BIAFINE® Topical Emulsion to the affected area(s) should continue during any subsequent physical therapy treatments.

### **Radiation Dermatitis**

- Apply a generous amount of BIAFINE® Topical Emulsion three times per day, seven days a week to the treated area(s), gently massaging the area(s) until BIAFINE® Topical Emulsion is completely absorbed.
- BIAFINE® Topical Emulsion may be applied as indicated by the treating physician (**see Warnings**).
- Continue to apply BIAFINE® Topical Emulsion as described above until the skin has fully recovered.
- Do not interrupt applications during the course of radiation therapy, even for one day.
- Do not apply BIAFINE® Topical Emulsion 4 hours prior to a radiation session.

### **Ingredients**

BIAFINE® Topical Emulsion contains purified water, liquid paraffin, ethylene glycol monostearate, stearic acid, propylene glycol, paraffin wax, squalane, avocado oil, trolamine/sodium alginate, triethanolamine, cetyl palmitate, methylparaben (sodium salt), sorbic acid (potassium salt), propylparaben (sodium salt), and fragrance.

### **How Supplied**

BIAFINE® Topical Emulsion is supplied in tubes in the following sizes:

1.5 oz. (45 g) tube

product code 0187-5110-45

3 oz. (90 g) tube

product code 0187-5110-90

Store at room temperature, do not freeze.

**Rx ONLY-** Prescription Medical Device: Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Distributed by:

Valeant Pharmaceuticals North America LLC

Bridgewater, NJ 08807 USA

For additional information: [www.biafine.com](http://www.biafine.com)

Made in France

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Rev. 12/12

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<i>Drawn by</i>	Sharon Metzger	12-13-12