

Médix Pharmaceuticals Americas, Incorporated Medical Safety Data Sheet

The information below is believed to be accurate and represents the best information currently available. However, Médix Pharmaceuticals Americas, Inc. makes no warranty expressed or implied, with respect to such information, and we assume no liability resulting from its use.

PRODUCT: BIAFINE® (Wound Dressing Emulsion)

SECTION 1: **GENERAL INFORMATION**

Trade Name: BIAFINE®

Chemical Name: Not applicable

Chemical composition: Demineralized hypotonic water, liquid paraffin, ethylene glycol, stearic acid, propylene glycol, paraffin wax, squalane, avocado oil, trolamine/sodium alginate, triethanolamine, cetyl palmitate, methyl paraben, sorbic acid, propyl paraben, Fragrance.

Formula: Patented, proprietary composition resulting in a stable, oil-in-water emulsion containing 75.5% water.

Supplied: 3.3 oz. epoxy lined aluminum tubes, case of 48 tubes.

Product Code

Tube: 712418 - 90010

Case: 712418 - 10001

SECTION 2: **HAZARDOUS INGREDIENTS**

None; the components in the product, as formulated, are non-toxic.

SECTION 3: **PHYSICAL DATA**

Appearance: White, moderately thick emulsion (cream)

Odor: Light flowery fragrance

Boiling Point: 250 degrees Fahrenheit

Freezing Point: 0 degrees Fahrenheit

Viscosity: 3000 cps

Water Solubility: The product is soluble in water, and is completely hydro-dispersable

pH: Neutral (7.0 - 7.2)

BIAFINE[®]

Wound Dressing Emulsion
For Topical Application Only

Product Description

BIAFINE[®] is a water-based wound dressing emulsion formulated to assist in the healing process of dermal wounds. When applied properly to a wound, BIAFINE[®] provides an optimum moist environment for the healing process, assists in the cleansing of the wound, and isolates the wound from bacterial and other external contamination.

Indications for Use

BIAFINE[®] is indicated for use in:

- Minor Abrasions
- Superficial Wounds
- Full Thickness Wounds, Pressure Sores, Dermal Ulcers including lower leg ulcers
- 1st and 2nd Degree Burns, including Sunburns
- Radiation Therapy-induced Skin Reactions
- Dermal Donor and Graft Sites

Contraindications

A known allergy to one of the ingredients in BIAFINE[®].

Warnings

In radiation therapy-induced skin reactions and/or in conjunction with ongoing radiation therapy, do not apply BIAFINE[®] to the radiation treatment area within 4 hours prior to a radiation session. BIAFINE[®] should be applied immediately following radiation sessions (see Instructions for Use in Radiation Therapy-Induced Skin Reactions).

Do not apply BIAFINE[®] to dermal grafts until after the graft has successfully taken.

Precautions and Observations

1. For the treatment of any dermal wound, consult a physician.
2. BIAFINE[®] is non-toxic, however it is for external use only and should not be ingested or taken internally.
3. BIAFINE[®] does not contain a sun screen and should not be used prior to or during extensive exposure to the sun.
4. Do not use BIAFINE[®] in a bleeding wound until the bleeding has stopped.
5. The use of BIAFINE[®] on skin rashes due to allergies has not been studied sufficiently and is therefore not recommended.
6. Following the application of BIAFINE[®], a temporary tingling sensation may occur (for 10-15 minutes) which is due to the stimulation of the micro circulation at the wound site.
7. If clinical signs of infection are present, appropriate anti-bacterial treatment should be initiated. Use of BIAFINE[®] must be continued during the anti-infective therapy.
8. If conditions do not improve within 10 days, see a physician immediately.
9. Keep this and all medications out of the reach of children.

Instructions for Use

1st and 2nd Degree Burns, Including Sunburns

Take precaution in removing any clothing near the wounded area.

Apply BIAFINE® as soon as possible, on or around the affected area, in thick 1/4 to 1/2 inch layers until the skin no longer absorbs the product. A white waxy residue will remain. If pain from the burn persists, apply thinner layers of BIAFINE® until the pain has ceased.

Continue to apply BIAFINE® until the wounded area has healed completely. Application of BIAFINE® to the affected area should continue during any subsequent physical therapy treatments.

Wounds, Abrasions, Full Thickness Wound and Dermal Graft Site Management

Wash affected area with saline, clean water, a suitable wound cleanser, or a disinfectant.

Apply BIAFINE® on and around the affected area in thick layers, 1/4 to 1/2 inch thick.

If a gauze dressing is to be used, the gauze should be moistened.

Reapply BIAFINE® as described above every 24 to 48 hours or until the wound or lesion has healed.

For Donor Sites: Apply BIAFINE® after skin removal and cover with a moist dressing. Leave for 7 days.

For Dermal Grafts: Apply BIAFINE® to the graft site only after the graft has taken successfully. BIAFINE® can be washed away with a saline solution on clean water without causing damage to the newly formed tissues.

Radiation Therapy-Induced Skin Reactions

Apply a generous amount of BIAFINE®, three times per day to the treated area, gently massaging the BIAFINE® until it is completely absorbed. A white waxy residue will remain..

Do not apply BIAFINE® to the treatment area within 4 hours prior to a radiation session (See Warnings). Apply BIAFINE® immediately following the session and twice more during the day.

Continue to apply BIAFINE® until the skin has fully recovered. Consult your Radiation Therapist.

Ingredients

BIAFINE® consists of purified water, liquid paraffin, ethylene glycol, stearic acid, propylene glycol, paraffin wax, squalane, avocado oil, trolamine/sodium alginate, triethanolamine, cetyl palmitate, methyl paraben, sorbic acid, propyl paraben, fragrance.

How Supplied

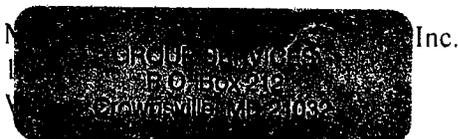
BIAFINE® Wound Dressing Emulsion

BIAFINE® is available in 3.3 oz. (93g), lined tubes. 48 tubes per case.

DONALD E. HOLLER, JR.
VP-Sales & Marketing

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BLAFINE® (Wound Dressing Emulsion)

SECTION 4: FIRE AND EXPLOSION INFORMATION

Fire: Non-flammable

Explosion Hazard: None

SECTION 5: HEALTH INFORMATION

Allergic reactions: None reported. The product is non-toxic and non-irritating. Allergy tests (i.e. Marzulli-Maibach) conducted on the product have always been negative.

Skin sensitivity: This products has been found to be non-sensitizing and non-cytotoxic (the product contains a natural preservative system which is bacteriostatic.) However, the product has actions on the healing process which may result in a tingling sensation when first applied to burns or other dermal wounds. This sensation should not be misinterpreted as a negative reaction to the product. To relieve the discomfort, wash the product off with cold water, wait three to ten minutes, then reapply. The sensation will not reoccur.

First Aid: Since the product does contain a soft soap, irritation may occur if placed into the eye. To relieve the discomfort, flush the eye with water.

Carcinogenicity: None

Teratogenicity: None

Mutagenicity: None

Incompatibilities: None

SECTION 6: ENVIRONMENTAL INFORMATION

Disposal: As with any medical product, dispose of in accordance with all federal, state, and local regulations.

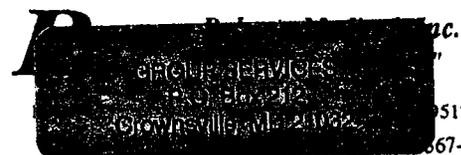
SECTION 7: SPECIAL PRECAUTIONS AND COMMENTS

To maintain optimum stability of the product, store at room temperature. Do not allow the product to remain in conditions of over 125 degrees or below 32 degrees Fahrenheit for any extended period of time, since these conditions will promote the de-stabilization of the emulsion.

The product **DOES NOT** contain a sun screen, therefore it should not be used immediately **PRIOR** to extensive exposure to the sun or therapeutic radiation.

For Emergencies, contact MPA at:

**Médix Pharmaceuticals Americas, Inc.
1350 Connecticut Ave, NW
Washington, D.C. 20036**



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