

ABRAVO TOPICAL EMULSION- dressing, wound, drug
Aletris Pharmaceuticals, LLC

Abravo Topical Emulsion

TOPICAL EMULSION

Rx Only

Abravo is a water-based, non-sterile 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, Abravo provides an optimum moist environment for the healing process and isolates the wound from harmful germs and other external contamination.

Abravo 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

Abravo 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.

- In radiation therapy, Abravo may be applied as directed by the treating physician. Do not apply 4 hours prior to a radiation session.
- Do not apply Abravo to dermal grafts until after the graft has successfully taken.
- Do not apply to the eyes or to mucous membranes.
- Not for internal use.
- Keep out of reach of children.

Caution:

- For the treatment of any dermal wound, consult a physician. Use Abravo only as directed.
- Abravo is non-toxic, it is for topical use only and should not be ingested or taken internally.
- Abravo does not contain a sunscreen and should not be used prior to extended exposure to the sun.
- The use of Abravo on skin rashes due to allergies has not been studied sufficiently and therefore is not recommended.
- Following the application of Abravo 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 Abravo may be continued during the anti-infective therapy.
- If condition does not improve within 10-14 days, consult a physician.
- Abravo may dissolve fuchsin when this dye is used to define the margins of the

radiation fields to be treated.

Abravo 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 Abravo 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 Abravo as described above every 24 to 48 hours or as directed until the wound or lesion has healed fully.
- For donor site management, apply Abravo after skin removal and cover with a moist dressing. Reapply as directed.
- For dermal graft site management, apply Abravo to the graft site only after the graft has taken successfully. Abravo 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 Abravo to burns, take precaution in removing any clothing in the affected area(s).
- Apply Abravo 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 Abravo until the pain has ceased.
- Continue to apply Abravo until the affected area(s) has healed completely.
- Application of Abravo to the affected area(s) should continue during any subsequent physical therapy treatments.

Radiation Dermatitis

- Apply a generous amount of Abravo three times per day, seven days a week to the treated area(s), gently massaging the area(s) until Abravo is completely absorbed.
- Abravo may be applied as indicated by the treating physician (see WARNINGS).
- Continue to apply Abravo 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 Abravo 4 hours prior to a radiation session.

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

Abravo is supplied in a 45-gram tube (60010-89071).

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).

Manufactured for:

Aletris Pharmaceuticals, LLC.
1636 Popp's Ferry Rd., Suite 218
Biloxi, MS 39532-2280
(228) 207-8112
www.aletrispharma.com

Call your doctor for medical advice about the side effects.
You may report side effects to FDA at 1-800-FDA-1088.

60010-89071



ALETRIS
PHARMACEUTICALS

Abravo

TOPICAL EMULSION

INGREDIENTS: Abravo contains purified water, liquid paraffin, ethylene glycol monostearate, stearic acid, propylene glycol, paraffin wax, squalane, avocado oil, triethylamine/sodium alginate, triethanolamine, cetyl palmitate, methylparaben (sodium salt), sorbic acid (potassium salt), propylparaben (sodium salt), and fragrance.

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Rx only

45g

Directions: For topical use only as directed by a health care professional.

For Use on Superficial Wounds and Full Thickness Wounds: Wash affected area(s) with saline or suitable wound cleanser. Apply Abravo in thick layers (1/4 to 1/2 inch) on and around affected area(s). If applying gauze dressing, moisten the dressing lightly before application. Reapply every 24-48 hours, or as directed.

For Use on 1st and 2nd Degree Burns Including Sunburns: Apply Abravo in thick layers (1/4 to 1/2 inch) on and around affected area(s) until it is absorbed into the skin. If pain is present, apply a thinner layer of Abravo to the affected area(s). Continue application until affected area(s) has healed completely.

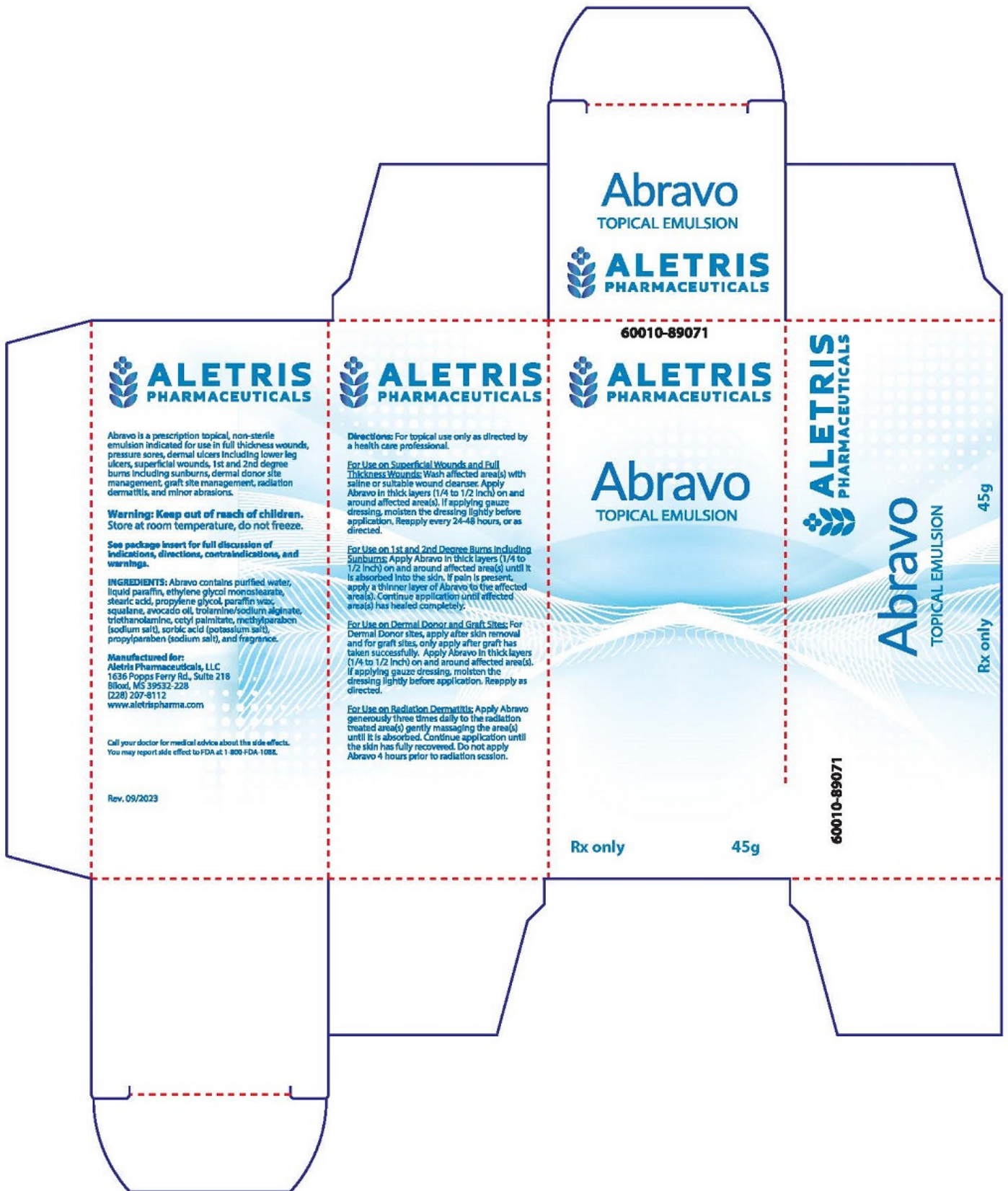
For Use on Dermal Donor and Graft Sites: For Dermal Donor sites, apply after skin removal and for graft sites, only apply after graft has taken successfully. Abravo in thick layers (1/4 to 1/2 inch) on and around affected area(s). If applying gauze dressing, moisten the dressing lightly before application. Reapply as directed.

For Use on Radiation Dermatitis: Apply Abravo generously three times daily to the radiation treated area(s) gently massaging the area(s) until it is absorbed. Continue application until the skin has fully recovered. Do not apply Abravo 4 hours prior to radiation session.

Non-sterile emulsion. See package insert for full discussion of indications, directions, contraindications, and warnings.

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dressing, wound, drug

Product Information

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|---------------------|-----------------------------|---------------------------|-----------------|
| Product Type | PRESCRIPTION MEDICAL DEVICE | Item Code (Source) | GS1:86001089071 |
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Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------------|---|----------------------|--------------------|
| 1 | GS1:86001089071 | 45 g in 1 TUBE; Type 0: Not a Combination Product | | |

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Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| premarket notification | K092878 | 10/28/2023 | |

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Labeler - Aletris Pharmaceuticals, LLC (118956541)

Revised: 11/2023

Aletris Pharmaceuticals, LLC