

**AVO CREAM- bur, surgical, general & plastic surgery emulsion**  
**Trigen Laboratories, LLC**

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**AVO Cream™ Topical Emulsion**

**DESCRIPTION**

AVO Cream™ 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, AVO Cream™ Topical Emulsion provides an optimum moist environment for the healing process and provides temporary wound protection from harmful germs and other external contamination.

**INDICATIONS FOR USE**

AVO Cream™ 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**

AVO Cream™ 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, AVO Cream™ Topical Emulsion may be applied as directed by the treating physician. Do not apply 4 hours prior to a radiation session.
- Do not apply AVO Cream™ 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 AVO Cream™ Topical Emulsion only as directed.
- AVO Cream™ Topical Emulsion is non-toxic. It is for topical use only and should not be ingested or taken internally.
- AVO Cream™ Topical Emulsion does not contain a sunscreen and should not be used prior to extended exposure to the sun.
- The use of AVO Cream™ Topical Emulsion on skin rashes due to allergies has not been studied sufficiently and therefore is not recommended.
- Following the application of AVO Cream™ 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 AVO Cream™ Topical Emulsion may be continued during the anti-infective therapy.

- If condition does not improve within 10-14 days, consult a physician.
- AVO Cream™ Topical Emulsion may dissolve fuchsin when this dye is used to define the margins of the radiation fields to be treated.

## **INSTRUCTIONS FOR USE**

AVO Cream™ 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 AVO Cream™ 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 AVO Cream™ 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 AVO Cream™ Topical Emulsion after skin removal and cover with a moist dressing. Reapply as directed.
- For dermal graft site management, apply AVO Cream™ Topical Emulsion to the graft site only after the graft has taken successfully. AVO Cream™ 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 AVO Cream™ Topical Emulsion to burns, take precaution in removing any clothing in the affected area(s).
- Apply AVO Cream™ 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 burn persists, apply thinner layers of AVO Cream™ Topical Emulsion until the pain has ceased.
- Continue to apply AVO Cream™ Topical Emulsion until the affected area(s) has healed completely
- Application of AVO Cream™ Topical Emulsion to the affected area(s) should continue during any subsequent physical therapy treatments.

### **Radiation Dermatitis**

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

## **INGREDIENTS**

AVO Cream™ Topical Emulsion contains algin, avocado oil, cetyl palmitate, glycol stearate, mineral oil, paraffin, potassium sorbate, propylene glycol, purified water, sodium methylparaben, sodium propylparaben, squalane, stearic acid and triethanolamine.

## **HOW SUPPLIED**

AVO Cream™ Topical Emulsion is supplied in a:

45 gram tube Product Code: 13811-565-45

90 gram tube Product Code: 13811-565-90

**STORAGE**

Store at controlled room temperature 15°C - 30°C (59°F - 86°F). [See USP]. Do not freeze.

**Call your doctor about side effects. You may report side effects by calling 888 9 TRIGEN (888-987-4436).**

**KEEP OUT OF THE REACH OF CHILDREN.**

**R<sub>x</sub> 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:**

TRIGEN Laboratories, LLC

Sayreville, NJ 08872

[www.trigenlab.com](http://www.trigenlab.com)



Rev. 01/15

**PRINCIPAL DISPLAY PANEL - 90 GRAM CARTON**

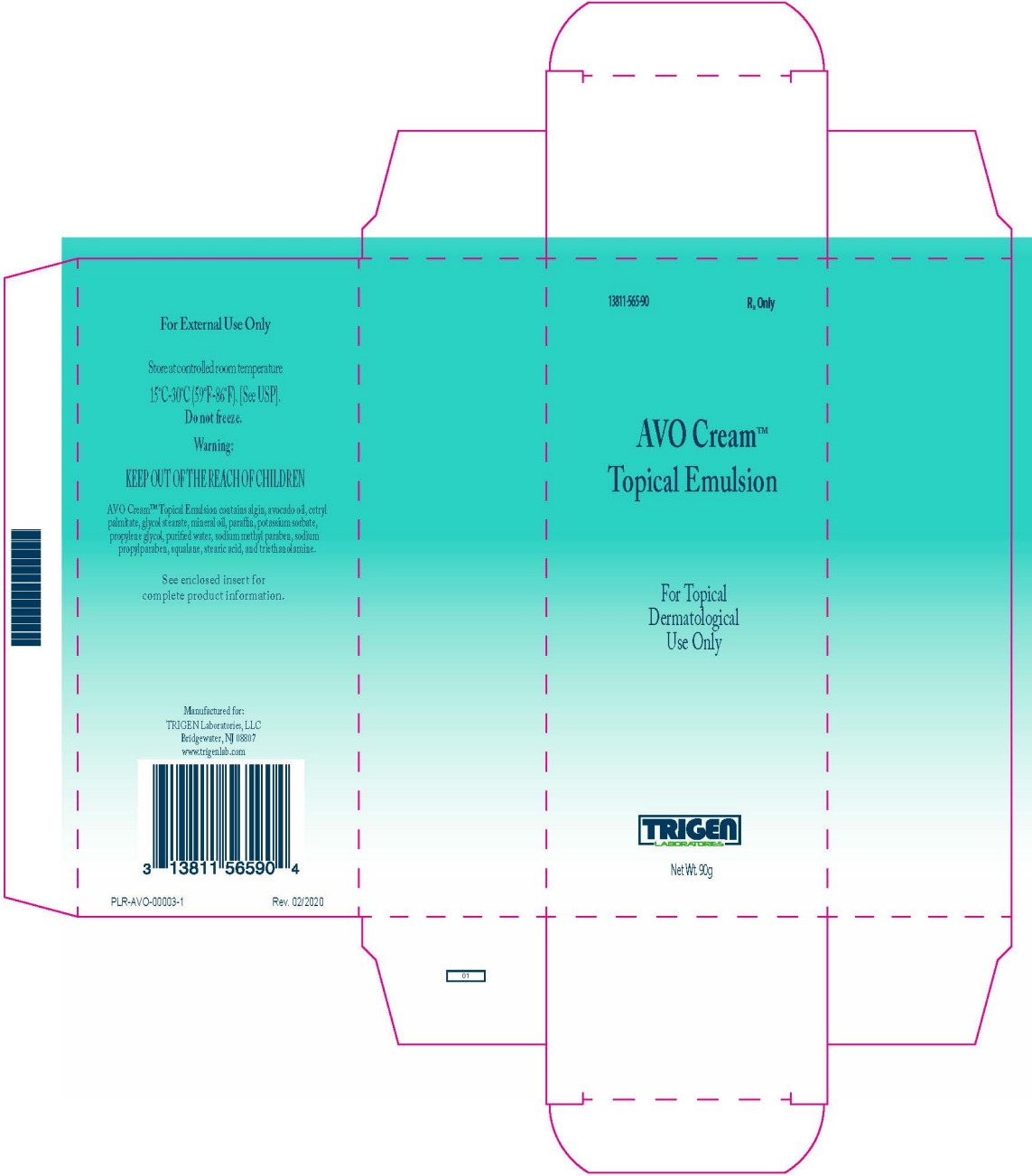
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 90 Gram Carton Label**

13811-565-90

Rx Only

AVO Cream<sup>TM</sup> Topical Emulsion

For Topical Dermatological Use Only



For External Use Only

Store at controlled room temperature  
15°C-30°C (59°F-86°F). (See USP)

Do not freeze.

Warning:

**KEEP OUT OF THE REACH OF CHILDREN**

AVO Cream™ Topical Emulsion contains algae, avocado oil, cetyl  
palmitate, glycol stearate, mineral oil, paraffin, potassium sorbate,  
propylene glycol, purified water, sodium methyl paraben, sodium  
propylparaben, squalene, stearic acid, and triethanolamine.

See enclosed insert for  
complete product information.

Manufactured for:  
TRIGEN Laboratories, LLC  
Bridgewater, NJ 08807  
www.trigenlab.com



PLR-AVO-00003-1

Rev. 02/2020

13811-56590

R, Only

# AVO Cream™ Topical Emulsion

For Topical  
Dermatological  
Use Only



Net Wt. 90g

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**PRINCIPAL DISPLAY PANEL - 45 GRAM CARTON**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 45 Gram Carton Label**

13811-565-45

Rx Only

AVO Cream™ Topical Emulsion

For Topical Dermatological Use Only





**PRINCIPAL DISPLAY PANEL - 90 GRAM TUBE**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 90 Gram Tube Label**

13811-565-90

Rx Only

AVO Cream™ Topical Emulsion

For Topical Dermatological Use Only

13811-565-90

Rx Only

# AVO Cream™ Topical Emulsion

For Topical  
Dermatological  
Use Only



Net Wt. 90g

**For External Use Only**

Store at controlled room temperature  
15°C-30°C (59°F-86°F). [See USP].

Do not freeze.

Warning:

**KEEP OUT OF THE REACH OF CHILDREN**

See enclosed insert for  
complete product information.

See crimp for  
lot # and expiration date.

Manufactured for:  
TRIGEN Laboratories, LLC  
Sayreville, NJ 08872  
www.trigenlab.com

#### INGREDIENTS

AVO CREAM™ Topical Emulsion  
contains algin, avocado oil, cetyl  
palmitate, glycol stearate, mineral oil,  
paraffin, potassium sorbate, propylene  
glycol, purified water, sodium  
methylparaben, sodium propylparaben,  
squalane, stearic acid and triethanolamine.



**PRINCIPAL DISPLAY PANEL - 45 GRAM TUBE**

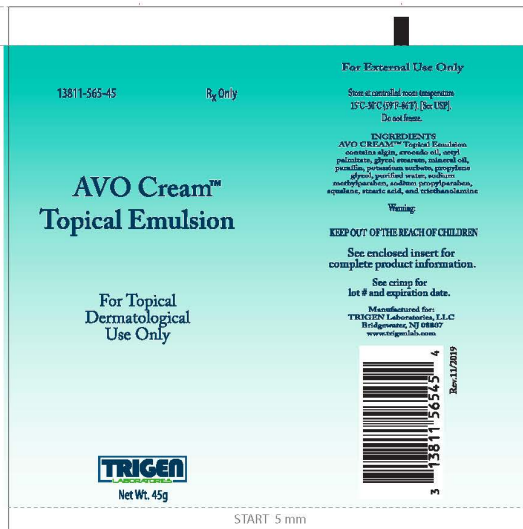
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 45 Gram Tube Label**

13811-565-45

Rx Only

AVO Cream™ Topical Emulsion

For Topical Dermatological Use Only



## AVO CREAM

bur, surgical, general & plastic surgery emulsion

### Product Information

<b>Product Type</b>	PRESCRIPTION MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:138 11-565
<b>Route of Administration</b>	TOPICAL		

### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	
INGR	<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
INGR	<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
INGR	<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
INGR	<b>SODIUM ALGINATE</b> (UNII: C269C4G2ZQ)	
INGR	<b>GLYCOL STEARATE</b> (UNII: 0324G66D0E)	
INGR	<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
INGR	<b>SQUALANE</b> (UNII: GW89575KF9)	
INGR	<b>AVOCADO OIL</b> (UNII: 6VNO72PFC1)	
INGR	<b>CETYL PALMITATE</b> (UNII: 5ZA2S6B08X)	
INGR	<b>METHYLPARABEN</b> (UNII: A218C7HI9T)	



INGR	<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
INGR	<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
INGR	<b>SORBIC ACID</b> (UNII: X045WJ989B)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:138 11-565-45	1 in 1 CARTON		
1		45 g in 1 TUBE; Type 0: Not a Combination Product		
2	NHRIC:138 11-565-90	1 in 1 CARTON		
2		90 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
PREMARKET NOTIFICATION	K110762	06/28/2013	

**Labeler** - Trigen Laboratories, LLC (830479668)

Revised: 1/2015

Trigen Laboratories, LLC