

ALADERM PLUS- dressing, wound, drug emulsion
Allegis Pharmaceuticals, LLC

Aladerm™
Plus

Rx Only
28595-282-02

DESCRIPTION

Aladerm Plus™ Rx Skin Emulsion is a water-based topical skin care emulsion that is indicated to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic and allergic contact dermatitis.

Aladerm Plus™ Rx Skin Emulsion contains natural extracts to moisturize the skin.

INDICATIONS FOR USE

As a prescription topical skin care emulsion to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic and allergic contact dermatitis. **Aladerm Plus™ Rx Skin Emulsion** helps maintain a moist wound and skin environment, which is beneficial to the healing process.

CONTRAINDICATIONS

Aladerm Plus™ Rx Skin Emulsion is contraindicated in persons with a known hypersensitivity to any of the components of the formulation.

PRECAUTIONS

Aladerm Plus™ Rx Skin Emulsion is for external use only.

Product should not be used prior to MRI Imaging, as it contains silver nanoparticles that can cause heating during these procedures.

Aladerm Plus™ Rx Skin Emulsion does not contain sunscreen.

If the condition does not improve within 10 days, consult a physician.

If clinical signs of infection are present, appropriate treatment should be initiated; use of **Aladerm Plus™**

Rx Skin Emulsion may be continued during anti-infective therapy.

Keep this and other similar products out of the reach of children.

DIRECTIONS FOR USE

Apply a small amount of **Aladerm Plus™ Rx Skin Emulsion** in sufficient quantity to

cover the affected skin area to be protected, and allow to dry. Reapply up to 4 times per day (or as needed).

INGREDIENTS

Deionized water, copolymer, vegetable oils from African palms, lidocaine HCl (less than 1%), and silver nanoparticles (as a preservative).

HOW SUPPLIED

Aladerm Plus™ Rx Skin Emulsion is available in a 60 ml bottle.

**PRESCRIPTION MEDICAL DEVICE:
FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A
PHYSICIAN**

SHAKE WELL BEFORE USING

STORE AT ROOM TEMPERATURE

Distributed by:

Allegis Pharmaceuticals, LLC
Canton, MS 39046

QUESTIONS: 1-866-633-9033

PRINCIPAL DISPLAY PANEL - 60 ml Bottle Label

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Aladerm™
Plus

PATENT PENDING

An Allegis Pharmaceuticals Product

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60ml (2oz)

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Rev. 06/21

ALADERM PLUS

dressing, wound, drug emulsion

Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	GS1:328595282022
Route of Administration	TOPICAL		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	GS1:328595282022	60 mL in 1 BOTTLE, SPRAY; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

Premarket Notification K141637

03/01/2025

Labeler - Allegis Pharmaceuticals, LLC (792272861)

Revised: 7/2023

Allegis Pharmaceuticals, LLC