DERPIXA- dressing, wound, occlusive Scite Pharma, LLC

ADVANCED FORMULATION

Derpixa

for cutaneous reactions

Rx Only

For topical use only

Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Description

Derpixa is an occlusive, non-resorbable, self-drying and transparent gel.

When used as directed Derpixa dries to form a protective layer that is gas permeable and waterproof which hydrates and protects compromised skin areas and superficial wounds from chemical and microbial invasion.

Derpixa helps to promote a moist healing environment.

This moist wound healing environment promotes faster re-epithelialization¹ and reduces the skin's acute inflammatory response.

Derpixa is suitable for large surface areas and contoured skin like head, face, hand and foot, as well as joints and hairy areas without the need for shaving.

1 Losi P et al. J Mater Sci Mater Med.2012;23(9):2235–43

Indication for use

Derpixa is intended to be used under the direction of healthcare practitioners in the management of cutaneous reactions.

Derpixa is indicated for use on all types of wounds, toxic and compromised skin including:

- Cutaneous reactions
- Pruritic, itchy skin
- Xerotic, dry skin
- Desquamation
- Fissures of skin and nail folds
- Blisters
- Medical Adhesive-Related Skin Injuries (MARSI)
- Erythema
- Infusion reactions
- Rashes, including: Maculopapular rash, hand-foot syndrome, GVHD, acneiform reaction, peri and appendageal (hair follicles, sweat glands)

Derpixa is indicated for the relief of dry, itching, flaking, peeling and irritated skin, as well as the symptomatic relief of pain, redness and heat sensation.

Derpixa may be directly applied to dry skin, open wounds and compromised or desquamating skin surfaces, including cutaneous rashes.

Derpixa gel is bacteriostatic and inert.

It contains no alcohols, parabens or fragrances.

Derpixa can be used with or without a secondary protective dressing.

Derpixa is suitable for children and people with sensitive skin.

Derpixa is intended for single patient use.

Directions for use



On the first use of 1 oz (28.5 g) tubes remove the cap, then the protective seal and close with the cap after use.

Ensure that the affected superficial area is clean and dry.

Apply a very thin layer of Derpixa directly to the affected area and allow the gel to dry.

When applied correctly to exposed areas, Derpixa should be dry in 5–6 minutes.

If it takes longer to dry you have probably applied too much.

Gently remove the excess with a clean tissue or gauze and allow the drying process to continue.

Once dry, Derpixa may be covered by sunscreen, cosmetics and clothing.

Derpixa should be applied at least twice daily to affected areas, as needed or as advised by your physician.

For best results Derpixa should be maintained in continuous contact with the skin (24 hours a day/7 days a week).

How much Derpixa do I need?

Derpixa gel is an advanced formulation that requires substantially less product per application than typical creams or gels.

Derpixa 1 oz (28.5 g) is enough to treat an area of 6×12 inch (15×30 cm) twice per day for 30 days.

Warning

- For external use only.
- Derpixa should not be placed in contact with the eyes.
- Derpixa should not be applied over topical medications unless advised by your physician.
- Derpixa may stain clothing if not completely dry. If staining occurs, dry cleaning should be able to remove it without damaging the fabric.
- For correct storage please reclose the tube tightly with the cap.
- If irritation occurs, discontinue use and consult your physician.
- Keep out of the reach of children.
- Do not use after the expiration (EXP) date printed on the tube. The expiration (EXP) date does not change once the tube has been opened.
- Do not use if the tube is damaged.

Contraindications

Do not administer to patients with known hypersensitivity to the ingredients of this product.

STERILE UNTIL OPENED

Ingredients: Dimethylpolysiloxane, dihydroxysiloxane and alkylmethylsiloxane.

How supplied

Derpixa 1 oz (28.5 g) tube

Product identification code: 79043-150-28

i	Consult instructions for use
\subseteq	Use by date
LOT	Batch code
STERILE R	Sterilized using irradiation
	Do not use if the tube is damaged
-86°F	Upper limit of temperature

Stratpharma AG Aeschenvorstadt 57 CH-4051 Basel Switzerland

Distributed by Allegis Pharmaceuticals Canton, MS 39046, USA

Date of preparation of this information: 10/2020

Stratpharma

Switzerland

scite

PHARMA

Questions:

1-866-633-9033

 \mathbf{CE}

DP000USENPI01-1020

PRINCIPAL DISPLAY PANEL - 28.5 g Tube Box

79043-150-28

Rx Only

For topical use only

ADVANCED FORMULATION

Derpixa

for cutaneous reactions

gel

1 oz

28.5 g

Indications for use: Derpixa is intended to be used under the direction of a healthcare practitioner in the management of cutaneous reactions.

Warning: For external use only. Keep out of the reach of children.

FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PRACTITIONER.

Ingredients: Dimethylpolysiloxane, dihydroxysiloxane and alkylmethylsiloxane.

See package insert for full information.

79043-150-28

R Only

For topical use only

gel

1oz

28.5g

ADVANCED FORMULATION

erpixa

for cutaneous reactions









Stratpharma AG Aeschenvorstadt 57 CH-4051 Basel, Switzerland







Distributed by: Allegis Pharmaceuticals Canton, MS 39046, USA

1-866-633-9033



tor cutaneous reactions

g c.85 ZOL

del

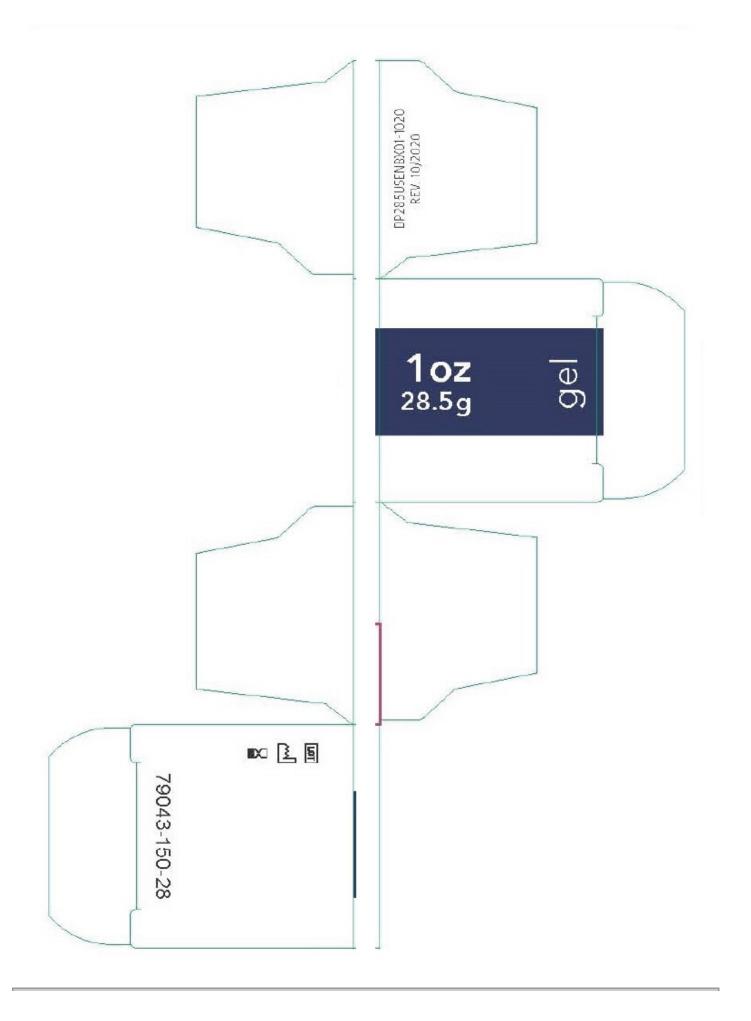
For topical use only

R Only

79043-150-28

erpixa

ADVANCED FORMULATION



DERPIXA

dressing, wound, occlusive

Product Information

Product Type MEDICAL DEVICE Item Code (Source) NHRIC:79043-150

Inactive Ingredients				
Ingredient Name	Strength			
DIMETHICO NE (UNII: 92RU3N3Y1O)				
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)				
DIDECYLDIMO NIUM CHLO RIDE (UNII: JXN40 O 9 Y 9 B)				

l	Packaging					
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
l	1 NHRIC:79043-150-28	1 in 1 BOX				
	1	28.5 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			
Exempt device	NAD	12/15/2020				

Labeler - Scite Pharma, LLC (117555106)

Revised: 1/2021 Scite Pharma, LLC