

**STRATAXRT- dressing, wound, occlusive**  
**Marnel Pharmaceuticals, Inc.**

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**STRATAXRT**

**Rx Only**

**For Topical Use Only**

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

**[EN] Description**

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

When used as directed StrataXRT 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.

StrataXRT helps to promote a moist wound healing environment.

This moist wound healing environment promotes faster re-epithelialization\* and reduces the skin's acute inflammatory response seen with both dry and moist desquamation.

In dry desquamation, StrataXRT protects the fragile epidermis and maintains the skin's integrity, preventing the outmost layers from excessive sloughing.

In moist desquamation, StrataXRT protects the dermal stroma from long-term deterioration and reduces the risk of infection.

StrataXRT is suitable for large surface areas and contoured skin like the breasts, face, back and pelvic area, as well as joints and hairy areas without the need for shaving.

**Indication for use**

StrataXRT is intended to be used under the direction of healthcare practitioners in the management of radiation dermatitis.

StrataXRT is indicated for use on all types of radiation dermatitis, toxic and compromised skin and superficial wounds resulting from radiation therapy.

StrataXRT 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.

StrataXRT may be directly applied to superficial wounds and areas where skin integrity has been compromised.

StrataXRT is bacteriostatic and inert.

StrataXRT contains no alcohols, parabens or fragrances.

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

StrataXRT is suitable for children and people with sensitive skin.

StrataXRT is intended for single patient use.

**Directions for use**

On the first use of 1.75 oz (50g) tubes, remove the cap, then the protective seal and close with the cap after use.

Ensure that the affected skin or superficial wound is clean and dry.

Gently pat dry as much excess exudate or wound fluid from the area as possible prior to gel application.

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

When applied correctly to exposed areas, StrataXRT 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, StrataXRT may be covered by sunscreen, cosmetics and clothing.

StrataXRT should be applied once or twice daily to affected areas or as advised by your physician.

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

StrataXRT does not need to be removed prior to radiation therapy.

### **How much StrataXRT do I need?**

StrataXRT gel is a unique formulation that requires substantially less product per application than typical creams or gels.

**StrataXRT 1.75 oz (50g)** is enough to treat an area of 6x12 inch (15x30 cm) twice a day for 30 days.

### **Warning**

- For external use only.
- StrataXRT should not be placed in contact with the eyes.
- StrataXRT should not be applied over topical medications unless advised by your physician.
- StrataXRT 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 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:**

StrataXRT 1.75oz (50g) tube

### **Product identification code**

73661-420-50

<b>Stratpharma</b> SX050USENBX03-0420	
Product: StrataXRT - Radiation Dermatitis Therapy Gel	APPROVALS
Article: Box, 50g	Marketing:
Country: USA	Medical:
Language: English	Regulatory:
Activity: Draft	
Version: Draft Version 5, 04.05.2020	Art Work by: zwiwest.malagzandwest.ch
Colors: #000000, #000000, #000000, #000000	
Variables: UV Variable - Dispersion Version (0) separate EPS-File	



## STRATAXRT

dressing, wound, occlusive

### Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:73661-420
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### Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6 Y)	
CAPRYL YL TRISILOXANE (UNII: Q95M2P1KJL)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:73661-420-50	1 in 1 BOX		
1		50 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	06/02/2020	

**Labeler** - Marnel Pharmaceuticals, Inc. (080161449)

## Establishment

Name	Address	ID/FEI	Business Operations
Stratpharma AG		483232695	manufacture

Revised: 7/2020

Marnel Pharmaceuticals, Inc.