

STRATACTX- dressing, wound, occlusive
Marnel Pharmaceuticals, Inc.

StrataCTX

Rx Only

For topical use only

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

[EN] Description

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

When used as directed StrataCTX 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.

StrataCTX helps to promote a moist healing environment.

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

StrataCTX 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.

Indication for use

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

StrataCTX 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)

StrataCTX 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.

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

StrataCTX gel is bacteriostatic and inert.

It contains no alcohols, parabens or fragrances.

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

StrataCTX is suitable for children and people with sensitive skin.

StrataCTX 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 superficial area is clean and dry.

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

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

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

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

How much StrataCTX do I need?

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

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

Warning:

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

StrataCTX 1.75 oz (50g) tube

Product identification code:

73661-421-50

Stratpharma		CT050USENBX01-0420
Product:	StrataCTX	APPROVAL:
Article:	001-50	Manufacturer:
Country:	USA	Medical:
Language:	English	Regulatory:
Activity:	Drug	
Version:	01/16/2020	Author(s):
Color:	Blue, White, Yellow, Red, Pink	Print:
Barcode:	73661-421-50	Export Version:



STRATACTX

dressing, wound, occlusive

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:73661-421
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Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
DIDECYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:73661-421-50	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	06/05/2020	

Labeler - Marnel Pharmaceuticals, Inc. (080161449)

Establishment

Name	Address	ID/FEI	Business Operations
Stratpharma AG		483232695	manufacture

Revised: 6/2020

Marnel Pharmaceuticals, Inc.