

NIVATOPIC PLUS- dressing, wound, drug cream
TAGI Pharma Inc.

NIVATOPIC™
Plus
Cream

FOR TOPICAL DERMATOLOGICAL AND EXTERNAL USE ONLY.

Rx Only

INDICATIONS FOR USE

NIVATOPIC Plus is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. NIVATOPIC Plus also helps to relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

CONTRAINDICATIONS

NIVATOPIC Plus is contraindicated in persons with a known hypersensitivity to any of the components of the formulation.

WARNINGS

Use only as directed.

Keep out of the reach of children.

Avoid contact with eyes.

For topical use only.

Not for ophthalmic use.

Do not apply within four hours prior to a radiation session.

PRECAUTIONS AND OBSERVATIONS

- NIVATOPIC Plus does not contain a sunscreen and should not be used prior to extended exposure to the sun.
- If clinical signs of infection are present, appropriate treatment should be initiated; use of NIVATOPIC Plus may be continued during the anti-infective therapy.
- If the condition does not improve within 10-14 days, consult a physician.
- NIVATOPIC Plus may dissolve fuchsin when this dye is used to define the margins of the radiation fields to be treated.

DIRECTIONS - CREAM

Dispense NIVATOPIC Plus Cream into palm of hand and apply to affected area three times per day, or as directed by a physician. Massage gently into the skin until completely absorbed. If the skin is broken, cover with appropriate dressing.

INGREDIENTS

Water, Glycerin, Ethylhexyl Palmitate, Cetearyl Alcohol, Propylene Glycol, Dicetyl Phosphate, Theobroma Grandiflorum Seed Butter, Petrolatum, Dimethicone, Steareth-10, Cetareth-10 Phosphate. Hydroxypropyl Bispalmitamide MEA (Ceramide), Tocopheryl Acetate. Methylparaben. Disodium EDTA, Propylparaben, Sodium Hyaluronate and Sodium Hydroxide.

HOW SUPPLIED

NIVATOPIC Plus Cream is available in 100 g tubes (NDC 51224-450-10) and 450 g jars (NDC 51224-450-20)

CAUTION Federal law restricts this device to sale by or on the order of a physician or other licensed health care practitioner.

Store between 59° and 86°F (15° and 30°C). Protect from freezing.

DISTRIBUTED BY:

Tagi Pharma, Inc.

722 Progressive Lane Rm 205

South Beloit, IL 61080

www.tagipharma.com

PRINCIPAL DISPLAY PANEL - 100 g Tube Label

51224-450-10

NIVATOPIC™

Plus

tagiPHARMA

That's A Good Idea

Topical Use Only

Rx Only

Net Wt 100 g (3.5 oz)

51224-450-10

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See package insert for full discussions of indications, directions, contraindications and warnings.

Store between 59°F - 86°F (15°C - 30°C).

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Topical Use Only

Rx Only
Net Wt 100g (3.5 oz)

NIVATOPIC PLUS

dressing, wound, drug cream

Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	NHRIC:51224-450
Route of Administration	TOPICAL		

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
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INGR	water (UNII: 059QF0KO0R)	
INGR	glycerin (UNII: PDC6A3C0OX)	
INGR	ethylhexyl palmitate (UNII: 2865993309)	
INGR	cetostearyl alcohol (UNII: 2DMT128MIS)	
INGR	propylene glycol (UNII: 6DC9Q167V3)	
INGR	dihexadecyl phosphate (UNII: 2V6E5WN99N)	
INGR	theobroma grandiflorum seed butter (UNII: I711F13FXM)	
INGR	petrolatum (UNII: 4T6H12BN9U)	
INGR	dimethicone (UNII: 92RU3N3Y1O)	
INGR	steareth-10 (UNII: FD0913P475)	
INGR	cetareth-10 phosphate (UNII: 099WOY1SA3)	
INGR	.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
INGR	methylparaben (UNII: A2I8C7HI9T)	
INGR	edetate disodium (UNII: 7FLD91C86K)	
INGR	propylparaben (UNII: Z8IX2SC1OH)	
INGR	hyaluronate sodium (UNII: YSE9PPT4TH)	
INGR	sodium hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:51224-450-20	4 in 1 CASE		
1		1 in 1 CARTON		
1		450 g in 1 JAR; Type 0: Not a Combination Product		
2	NHRIC:51224-450-10	4 in 1 CASE		
2		1 in 1 CARTON		
2		100 g in 1 TUBE; Type 0: Not a Combination Product		
3	NHRIC:51224-450-01	24 in 1 CASE		
3		1 in 1 CARTON		
3		10 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	K132329	06/05/2014	

Labeler - TAGI Pharma Inc. (963322560)

Revised: 1/2016

TAGI Pharma Inc.