LEAF INSERT

MYCOSARAN VAGINAL CREAM 20mg/g
(MICONAZOLE NITRATE USP)

LABEL CLAIM:
Each gram Contains :
Miconazole Nitrate ……20mg
USP Specs.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Quantity (mg) per gm	Quantity(kg) per batch	Role of Ingredient
Miconazole Nitrate	20.000	[1]10.000	Active Ingredient
Benzoic Acid	1.5000	0.750	Preservative
Cetyl Alcohol	65.335	32.668	Stiffening agent
Emulsifying Wax	4.000	2.000	Emulsifying Agent
Glycerin Pure	33.065	16.532	Humectant and Emollient
Glyceryl Monostearate	60.665	30.332	Emulsifying Agent
Lanolin Anhydrous	33.335	16.668	Hydrophobic
Liquid Paraffin	13.335	6.668	Emollient
Methyl Paraben	1.700	0.850	Preservative
Propyl Paraben	0.300	0.150	Preservative
Stearic Acid	89.335	44.668	Thickener and Emulsion Stabilizer
White Petroleum Jelly	26.665	13.332	Hydrophobic Vehicle and Emollient Base
Tween 80 (Poly Sorbate 80)	20.000	10.000	Surface Agent Acting
De-Ionized Water	630.765	315.382	Vehicle

[1]Quantity at 100% potency basis.

Excipients with known effects**:**

Benzoic Acid: Irritation of the skin, mucous membranes and eyes (local application), risk of jaundice in the new-born (injections)

Lanolin Anhydrous: Eczema

PHARMACEUTICAL FORM

White Colored semisolid cream.

CLINICAL DATA:

THERAPEUTIC INDICATIONS:

For the treatment of mycotic infections of the skin and nails and superinfections due to Gram- positive bacteria.

DOSAGE AND ADMINISTRATION:

Route of administration:

Cutaneous use.

Recommended dosage:

For all ages:

Fungal infections of the skin: Apply some cream to the lesions two times daily. Rub the cream into the skin with your finger until it has fully penetrated. If the powder is used with the cream, a once daily application of both formulations is recommended. The duration of therapy varies from 2 to 6 weeks depending on the localisation and the severity of the lesion. Treatment should be continued at least one week after disappearance of all signs and symptoms.

Nail infections: Apply the cream once or twice daily to the lesions. Treatment should be prolonged for 10 days after all lesions have disappeared to prevent relapse.

CONTRA-INDICATIONS:

Mycosaran Cream is contraindicated in individuals with a known hypersensitivity to Miconazole/Miconazole nitrate, other imidazole derivatives or to any of the excipients

WARNING & PRECAUTION FOR USE:

Cream must not come into contact with the mucosa of the eyes.

Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with Cream and with other Miconazole topical formulations (see Adverse Reactions). If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued.

This medicine contains Benzoic acid. Benzoic acid may cause local irritation. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

DRUG INTERACTIONS:

Miconazole administered systemically is known to inhibit CYP3A4/2C9. Due to the limited systemic availability after topical application, clinically relevant interactions are rare. However, in patients on oral anticoagulants, such as warfarin, caution should be exercised and anticoagulant effect should be monitored.

REPRODUCTION, PREGNANCY AND BREAST-FEEDING:

Pregnancy

In animals Miconazole nitrate has shown no teratogenic effects but is foetotoxic at high oral doses. Only small amounts of Miconazole nitrate are absorbed following topical administration. However, as with other imidazoles, Miconazole nitrate should be used with caution during pregnancy.

Lactation

Topically applied Miconazole is minimally absorbed into the systemic circulation, and it is not known whether Miconazole is excreted in human breast milk. Caution should be exercised when using topically applied Miconazole products during lactation.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Cream has no influence on the ability to drive and use machines.

UNDESIRABLE EFFECTS:

Adverse drug reactions reported among 834 patients who received Miconazole nitrate 2% cream (n=426) and/or placebo cream base (n=408) in 21 double- blind clinical trials are presented in Table 1 below. Moreover, adverse drug reactions from spontaneous reports during the worldwide post-marketing experience with Mycosaran that meet threshold criteria are included in Table 1. The adverse drug reactions are ranked by frequency, using the following convention:

Very common ≥ 1/10

Common ≥ 1/100 and <1/10

Uncommon ≥ 1/1,000 and <1/100

Rare ≥ 1/10,000 and <1/1,000

Very rare <1/10,000, including isolated reports

Adverse reactions obtained from clinical studies and post-marketing surveillance are presented by frequency category based on incidence in clinical trials or epidemiology studies, when known.

Table 1: Adverse reactions reported in clinical trials and post-marketing experience

System Organ Class	Adverse Reactions	
	Frequency Category	
	Uncommon (≥ 1/1,000 to <1/100)	Not known
Immune System Disorders		Anaphylactic reaction Hypersensitivity
Skin and Subcutaneous Tissue Disc	Skin burning sensation Skin inflammation Skin hypopigmentation	Angioedema Urticaria Contact dermatitis Rash Erythema Pruritus
General Disorders and Administrat Conditions	Application site irritation Application site burning Application site pruritus Application site reaction NOS Application site warmth	

OVERDOSE

Symptoms

Cutaneous use: Excessive use can result in skin irritation, which usually disappears after discontinuation of therapy.

Accidental ingestion: Stomach irritation may occur.

Treatment

Mycosaran Cream is intended for cutaneous use, not for oral use. If accidental ingestion of large quantities of the product occurs, use appropriate supportive care.

PHARMACOLOGICAL PROPERTIES:

Pharmacodynamic properties (with Pharmacotherapeutic class):

Pharmacotherapeutic classification: (Antifungals for dermatological/topical use; imidazole derivative) *ATC code*: D01A C02.

The therapeutic class: TOPICAL ANTIFUNGALS

Miconazole nitrate is an imidazole antifungal agent and may act by interfering with the permeability of the fungal cell membrane. It possesses a wide antifungal spectrum and has some antibacterial activity.

Pharmacokinetics:

Absorption: There is little absorption through skin or mucous membranes when Miconazole nitrate is applied topically.

Distribution: Absorbed Miconazole is bound to plasma proteins (88.2%) and red blood cells (10.6%).

Metabolism and Excretion: The small amount of Miconazole that is absorbed is eliminated predominantly in faeces as both unchanged drug and metabolites.

PHARMACEUTICAL DATA:

Store below 30ºC.
Protect from sunlight and moisture.
Keep out of the reach of children.

PRESENTATION:

Miconazole Nitrate Vaginal Cream for commercial use is available in Aluminium collapsible tube with polyethylene cap & measured dose applicator. Each filled tube & applicator is packed in printed carton with the product name and batch details along with the information of the manufacturer and distributor. Stability studies show no interaction between Aluminum collapsible tube and all the formulation ingredients.

MEDECINE ON PRESCRIPTION ONLY: List 1

MARKETING AUTHORIZATION HOLDER:

SARAN PHARMA
ABIDJAN COCODY 2 PLATEAUX DERRIERE L'EN, RUE J5, LOT 269, SECTION KX PARCELLE 104, 08 BP 3121 ABIDJAN 08 RCI

MANUFACTURED BY:

Nabiqasim Industries (Pvt.) Ltd.
17/24, Korangi Industrial Area,
Karachi – Pakistan.

DATE OF LAST REVISION:

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