Bharat Parenterals Limited
Registered Office & Works:
Vill. Haripura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.
Tele Fax : (02667)-251679, 251680, 251669, 99099 28332.
E-mail: bplbrd@bplindia.in, info@bplindia.in, Web.: www.bplindia.in
CIN NO: U24231GJ1992PLC018237

BIOMESTATIN - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

1.1. Name of the medicinal product:

Generic Name/INN Name:

Nystatin Vaginal Tablets USP

Trade Name: BIOMESTATIN

1.2 Strength:

Each uncoated tablet contains

Nystatin USP -1, 00,000 Units

1.3 Pharmaceutical form:

Vaginal Tablet

2. Qualitative and Quantitative composition:

Sr. No.	Ingredients	Spec.	Label Claim	Qty./Tablet (mg)	%w/w	Function
Dry Mixing						
1.	Nystatin USP (1,00,000) Units	USP	1,00,000 Units	19.49	1.821	Active
2.	Maize Starch	BP	---	636.71	59.506	Diluent
3.	Lactose Monohydrate	BP	---	325.00	30.374	Diluent
Binding						
4.	Povidone K-30 BP	BP	---	47.000	4.393	Binder
5.	Isopropyl Alcohol	BP	---	340.00	---	Solvent
Lubrication-						
6.	Magnesium Stearate	BP	---	5.2000	0.486	Lubricant
7.	Purified Talc	BP	---	8.6000	0.804	Lubricant
8.	Colloidal Anhydrous silica	BP	---	28.000	2.617	Disintegrant
Total				**1410.0**		
Loss of Moisture & Solvent				**340.00**		
Total Weight of uncoated tablet				**1070.000**	**100.00**	

BHARAT PARENTERALS LTD. VADODARA INDIA

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3. Pharmaceutical form:

Dosage Form: Vaginal Tablet

Visual & Physical characteristics of the product

A pale yellow coloured oval shape, biconvex, uncoated tablet, having embossed "Conical Flask B" on one side of the tablets.

4. Clinical particulars:

4.1. Therapeutic indications:

Nystatin Vaginal Tablets, USP are effective for the local treatment of vulvovaginal candidiasis (moniliasis).

4.2. Posology and method of administration:

The usual dosage is one tablet (100,000 units nystatin) daily for two weeks. The tablets should be deposited high in the vagina by means of the applicator. "Instructions for the Patient" are enclosed in each package.

4.3. Contraindications:

This preparation is contraindicated in patients with a history of hypersensitivity to any of its components.

4.4 Special warnings and precautions for use:

General: Discontinue treatment if sensitization or irritation is reported during use.

Information for Patients: The patient should be informed of symptoms of sensitization or irritation and told to report them promptly.

The patient should be warned against interruption or discontinuation of medication even during menstruation and even though symptomatic relief may occur within a few days.

The patient should be advised that adjunctive measures such as therapeutic douches are unnecessary and sometimes inadvisable, but cleansing douches may be used by nonpregnant women, if desired, for esthetic purposes.

Laboratory Tests: If there is a lack of response to Nystatin Vaginal Tablets USP, appropriate microbiological studies should be repeated to confirm the diagnosis and rule out other pathogens before instituting another course of antimycotic therapy.

4.5 Interaction with other medicinal products and other forms of interaction:

BHARAT PARENTERALS LTD. VADODARA INDIA

Tell your doctor of all prescription and nonprescription medication you may use, especially of: oral antibiotics or antifungals (e.g., metronidazole, nystatin), blood thinners (e.g., warfarin), phenytoin, lithium, disulfiram. Do not start or stop any medicine without doctor or pharmacist approval.

4.6 Pregnancy and lactation:

Teratogenic Effects: Pregnancy Category A. There have been no reports that use of Nystatin Vaginal Tablets by pregnant women increases the risk of fetal abnormalities or affects later growth, development and functional maturation of the child. Nevertheless, because the possibility of harm cannot be ruled out, Nystatin Vaginal Tablets should be used during pregnancy only if the physician considers it essential to the welfare of the patient.

4.7. Effects on ability to drive and use machines:

Nystatin Vaginal Tablets has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects:

May cause (rarely): local irritation, allergic reactions.

4.9. Overdose:

If overdose is suspected, contact your local poison control center or emergency room immediately. This product may be harmful if swallowed. Symptoms of overdose may include nausea and vomiting, loss of coordination, tingling or numbness of the fingers, or seizures.

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Antifungal agent; binds to sterols in cell membrane resulting in permeability changes and leakage of intracellular content

Pharmacotherapeutic Group: Antifungal

ATC Code: D01AA01

5.2 Pharmacokinetic properties:

Absorption: Systemic absorption unlikely; poorly absorbed from intact skin and mucous membranes.

5.3 Preclinical safety data

BHARAT PARENTERALS LTD. VADODARA INDIA

No long-term animal studies have been performed to evaluate the carcinogenic potential of nystatin. No studies have been performed to determine the mutagenicity of nystatin or its effect on male or female fertility.

6. Pharmaceutical particulars:

6.1. List of Excipients:

Maize Starch

Lactose Monohydrate

Povidone K-30 BP

Magnesium Stearate

Purified Talc

6.2 Incompatibilities:

None known.

6.3. Shelf life:

36 months

6.4. Special precautions for storage:

Do not store above 30°C.

6.5. Nature and contents of container:

150 CC Plastic HDPE Jar with induction cap round white colour &

1×15 Tablets Alu-PVC blister pack in one monocarton

6.6. Special precautions for disposal:

No special requirement.

7. Applicant

Name and Address of Applicant

M/s. Biomedicine Sckivs Pharm.Nig Ltd,

Premise Address: No. 16, Anionwu Street Odoakpu, P.O.BOX:7846, Onitsha Nigeria,

Tel: +234803507884, +2348024517997.

E-mail: sckivspharm@yahoo.com

Name and Address of manufacturer:

M/s. BHARAT PARENTERALS LIMITED

Survey No. 144 &146, Jarod Samlaya Road,

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