1.6.1

Prescribing Information (Summary of Product Characteristics)

1.6.1.1 Name of the medicinal Product

Nystatin Vaginal Inserts USP 100000 I.U.

1.6.1.1.1 Strength

100000 I.U.

1.6.1.1.2 Pharmaceutical Form

Vaginal Inserts

1.6.1.2 Qualitative and Quantitative Composition

1.6.1.2.1 Qualitative declaration

Nystatin USP

1.6.1.2.2 Quantitative declaration

Sr. No.	Ingredients	Specification	Overages	Standard Quantity (mg/insert)	Reason for Inclusion
1.	Nystatin (A)	USP	Nil	22.730	Antimycotic Polyene Antibiotic
2.	Lactose (Lactose Monohydrate) (C)	BP	--	783.270	Diluent
3.	Colloidal Anhydrous Silica (Aerosil)	BP	--	10.00	Diluent
4.	Maize Starch	BP	--	25.020	Binding agent
5.	Povidone (P.V.P.K-30)	BP	--	15.00	Disintegrant
6.	Magnesium Stearate	BP	--	10.00	Lubricant
7.	Purified Talc	BP	--	10.00	Lubricant
8.	Colloidal Anhydrous Silica (Aerosil)	BP	--	11.00	Diluent

9.	Sodium Starch Glycolate (Type-A)	BP	--	45.00	Disintegrant
10.	Microcrystalline Cellulose (PH 102)	BP	--	200.00	Disintegrant
11.	Purified Water	BP	--	Q.S	Vehicle

Note:

(A) = Quantity to be calculated on the basis of its potency.

(C) = Quantity of Lactose (Lactose Monohydrate)BP to be reduced against incremental increase in quantity of Nystatin USP due to assay compensation.

Latest version of pharmacopoeia is used.

1.6.1.3 Pharmaceutical Form

Solid Dosage Form, Vaginal Inserts.

Off white to pale yellow coloured, almond shaped, uncoated tablet, plain on both sides.

1.6.1.4 Clinical Particulars

1.6.1.4.1 Therapeutic Indications

Nystatin Vaginal Tablets are effective for the local treatment of vulvovaginal candidiasis (moniliasis). The diagnosis should be confirmed, prior to therapy, by KOH smears and/or cultures. Other pathogens commonly associated with vulvovaginitis (Trichomonas and Haemophilus vaginal is) do not respond to nystatin and should be ruled out by appropriate laboratory methods.

1.6.1.4.2 Posology and Method of Administration

Neovag Vaginal Tablets are inserted in the vagina. The usual dosage for the treatment of vaginal candidias is in both gravid and non-gravid patients is I to 2 tablets (100,000 to 200,000 units) intra vaginally daily for two weeks.

Note: Pregnant women should strictly foll ow the doctor's instructions.

1.6.1.4.3 Contraindications

Hypersensitivity reactions.

1.6.1.4.4 Special Warnings and Special Precautions for Use

Discontinue if sensitivity occurs. Pediatrics: Reduce dose necessary. Pregnancy & Lactation: No evidence of risk, Elderly: Safe.

1.6.1.4.5 Interaction with other medicinal products and other forms of interaction

Not Applicable.

1.6.1.4.6 Fertility, Pregnancy and Lactation

No evidence of risk.

1.6.1.4.7 Effects on ability To Drive and use Machines

Use caution if intending to drive or operate machinery.

1.6.1.4.8 Undesirable Effects

Neovag is virtually non-toxic and non-sensitizing and is well tolerated by most patients even on prolonged administration. If irritation or itching on vaginal application occurs discontinue medication immediately and consult the physician.

1.6.1.4.9 Overdose

No evidence noted.

1.6.1.5 Pharmacological Properties

Nystatin is both fungistatic and fungicidal in vitro against a wide variety of yeasts and yeast-like fungi. Nystatin interferes with the permeability of the cell membrane of sensitive fungi by binding to sterols. It's main action against Candida.

1.6.1.5.1 Preclinical Safety Data

Not Applicable.

1.6.1.6 Pharmaceutical Particulars

1.6.1.6.1 List of Excipients

Lactose (Lactose Monohydrate) (C)	BP
Colloidal Anhydrous Silica (Aerosil)	BP
Maize Starch	BP

Povidone (P.V.P.K-30)	BP
Magnesium Stearate	BP
Purified Talc	BP
Sodium Starch Glycolate (Type-A)	BP
Microcrystalline Cellulose (PH 102)	BP
Purified Water	BP

1.6.1.6.2 Incompatibilities

Not applicable.

1.6.1.6.3 Shelf Life

36 months

1.6.1.6.4 Special Precautions for Storage

Store below 30°C. Protect from light & moisture.

1.6.1.6.5 Nature and Contents of Container

10 tablets are strip packed. Such 10 strip is packed in a Printed Carton with Packing Insert.

1.6.1.6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

1.6.1.7 Marketing Authorization Holder And Manufacturing Site Addresses

1.6.1.7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

1.6.1.7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited

Trimul Estate, Khatraj, Taluka: Kalol,

District: Gandhinagar Gujarat, India.

Telephone no.: +91-79-41078096

Fax: +91-79-41078062

Email: hiren@lincolnpharma.com

Website: www.lincolnpharma.com

1.6.1.8 Marketing Authorization Number

To be included after obtaining first registration.

1.6.1.9 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

1.6.1.10 **Date of Revision of the Text**

1.6.1.11 Dosimetry (If Applicable)

Not Applicable

1.6.1.12 Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable