


## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

**GENERIC:** Nystatin Vaginal Inserts 100,000 IU

**BRAND NAME:** NYSKA-V

#### **VISUAL DESCRIPTION:**

Pale Yellow half capsule shaped biconvex uncoated tablets having mark “  ” debossed on one side and plain other side.

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated vaginal tablet (insert) contains:

Nystatin USP 100,000 IU

Excipients q.s.

### 3. PHARMACEUTICAL FORM:

Solid Dosage Form –Vaginal Inserts(Tablet)

### 4. CLINICAL PARTICULARS

#### **4.1 Therapeutic Indication:**

For local treatment of vulvovaginal candidiasis (moniliasis).

#### **4.2 Posology and method of administration:**

For vaginal infections in a dosage of 100,000 to 200,000 units, wet tablets in a water before use (1 to 2 tablets) and insert deep into the vagina by means of the applicator daily for 14 days.

OR

As directed by the physician

#### **DIRECTIONS FOR USE:**

Insert the vaginal tablets high into the vagina. They each come with a special applicator for inserting them and directions. Unwrap the vaginal tablets just before inserting them. Read the directions provided with the tablets and follow these steps:

1. Fill the special applicator to the level indicated.
2. Lie on your back with your knees drawn upward and spread apart.
3. Gently insert the applicator into your vagina and push the plunger to release the medication.
4. Withdraw the applicator and wash it with soap and warm water.
5. Wash your hands promptly to avoid spreading the infection.

Continue using Nystatin vaginal tablets even if you get your period during treatment.

#### **4.3 Contraindications:**

To be avoided in patients with known hypersensitivity to any of the components of these tablets.

#### **4.4 Warning and precautions for use**

In case of hypersensitivity reaction, the drug should be immediately withdrawn and appropriate measures to be taken.

#### **4.5 Drug Interactions**

Not relevant

#### **4.6 Pregnancy & Lactation**

##### **Pregnancy**

##### **Category A**

Systemic absorption of nystatin is negligible after topical, vaginal, or oral administration. However, as with all medicines, caution should be exercised when nystatin is administered to pregnant women.

##### **Lactation**

No data available

#### **4.7 Effects on ability to drive and use machines:**

Not relevant.

#### **4.8 ADVERSE EFFECTS**

Failure of contraceptive (Diaphragm) with vaginal pessaries. Should not be used concomitantly or if rubber is damaged. Prolonged use causes irritation.

#### **4.9 Overdose**

If overdose is suspected, contact your local poison control center or emergency room immediately.

### **5. PHARMACOLOGICAL PROPERTIES:**

#### **5.1 Pharmacodynamics properties:**

Pharmacotherapeutic group: Antifungals for topical use. ATC code: D01 AA01 Nystatin is an antifungal antibiotic active against a wide range of yeasts and yeast-like fungi, including *Candida albicans*.

#### **5.2 Pharmacokinetic properties**

Gastrointestinal absorption of nystatin is insignificant. Most orally administered nystatin is passed unchanged in the stool. In patients with renal insufficiency receiving oral therapy with conventional dosage forms, significant plasma concentrations of nystatin may occasionally occur.

#### **5.3 Preclinical safety data**

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.

### **5. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Microcrystalline Cellulose (ACCEL 102) BP, Sodium starch glycolate BP, Purified Talc BP, Croscarmellose sodium BP, Magnesium stearate BP.

#### **6.2 Incompatibilities**

Not Applicable

#### **6.3 Shelf Life**

36 Months

**6.4 Special precautions for storage:**

Do not store above 30°C. Protect from light.  
Keep the medicine out of reach of children.

**6.5 Nature and contents of container**

1x14's Strip pack.

**6.6 Special precautions for disposal and other handling**

Keep the medicine out of reach of children.

**7. APPLICANT**

Manufactured by:

 **S Kant**

HEALTHCARE Ltd.

**1802-1805, G.I.D.C., Phase III,**

**Vapi - 396 195. Gujarat, INDIA.**