

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

NYSTABS/Nystatin Tablets 500,000 Units

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Nystatin BP 525,000 Units (approximately 90.00 mg)

### **3 PHARMACEUTICAL FORM**

Tablet

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Candidiasis

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

Adults, including the Elderly:

1 tablet four times daily. This dose may be doubled. For prophylaxis a total daily dosage of 1 million units has been found to suppress the overgrowth of *C. albicans* in patients receiving broad-spectrum antibiotic therapy.

Administration should be continued for 48 hours after clinical cure to prevent relapse.

Children: Not recommended.

Route of administration: Oral

#### **4.3 Contraindications**

There are no known contra-indications to the use of Nystatin, except hypersensitivity to the ingredients in the product.

#### **4.4 Special warnings and precautions for use**

None stated

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None stated

#### **4.6 Pregnancy and lactation**

None stated

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

None stated

#### **4.8 Undesirable effects**

Nausea, vomiting and diarrhoea have occasionally been reported with doses of Nystatin exceeding 4 to 5 million units daily. Non systemic effects or allergic reactions have been associated with its oral use.

#### **4.9 Overdose**

Since the absorption of Nystatin from the gastro-intestinal tract is negligible, overdosage causes no systemic toxicity.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Nystatin exerts its effect by interaction with cell walls and cell membranes. Sterols present in the cell membrane are necessary for this effect. It has both fungistatic and fungicidal effects.

#### **5.2 Pharmacokinetic properties**

Nystatin is an anti-fungal antibiotic active against *Candida albicans* and a wide range of yeast-like fungi.

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

Not applicable

### **6 PHARMACEUTICAL PARTICULARS**

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

Pregelatinised maize starch, maize starch, lactose, sodium starch glycollate, magnesium stearate.

Shellac, povidone, talc, sucrose, E171, E124, E128 E110, E172.

#### **6.2 Incompatibilities**

None stated.

### **6.3 Shelf life**

36 months.

### **6.4 Special precautions for storage**

Store in a cool, dry place in well closed containers.  
Protect from light.

### **6.5 Nature and contents of container**

High density polystyrene with polythene lids and/or polypropylene containers with polypropylene or polythene lids and polyurethane/polythene inserts.

Pack sizes: 28 and 100.

### **6.6 Special precautions for disposal**

Use as directed by the physician.

## **7 MARKETING AUTHORISATION HOLDER**

Chelonia Healthcare Limited

Boumpoulinas 11, 3<sup>rd</sup> Floor

NICOSIA

CYPRUS

P.C. 1060

CYPRUS

**8     MARKETING AUTHORISATION NUMBER(S)**

PL 33414/0072

**9     DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

21/11/2008

**10    DATE OF REVISION OF THE TEXT**

21/11/2008