## 1.5 Product Information: MYCOREN TABLETS

### 1.5.1 Prescribing information (Summary of products characteristics):

**1. Name of the Medicinal Product: MYCOREN TABLETS**

**Strength:**

Nystatin 500,000 I.U

**Pharmaceutical form:** Tablet

**2. Qualitative and Quantitative composition:**

**Qualitative composition:**

| Sr. No. | Ingredient | Uses |
|---|---|---|
| 1. | Nystatin Ph. Eur, BP, USP | Active |
| 2. | Microcrystalline cellulose (MCC102) BP | Diluents |
| 3. | Sodium starch glycollate BP | Disintegrant |
| 4. | Magnesium stearate BP | Lubricant |
| 5. | Hydroxy propyl methyl cellulose USP | Polymer |
| 6. | Isopropyl alcohol BP | Solvent |
| 7. | Methylene chloride BP | Solvent |
| 8. | Maize starch BP | Dusting Powder |
| 9. | Purified Talc BP | Dusting Powder |
| 10. | Calcium Carbonate BP | Dusting Powder |
| 11. | Gum Acacia BP | Sub Coating |
| 12. | Gelatin BP | Sub Coating |
| 13. | Purified Talc BP | Sub Coating |
| 14. | Sucrose BP | Sub Coating |
| 15. | Titanium dioxide BP | Pigment |
| 16. | Sucrose BP | Colour Coat |
| 17. | Colour chocolate Brown IH | Pigment |
| 18. | Novoglow IH | Polishing |
| 19. | Isopropyl alcohol BP | Solvent |
| 20. | Methylene chloride BP | Solvent |

| CTD MODULE 1<br>ADMINISTRATIVE INFORMATION AND<br>PRODUCT INFORMATION | |
|---|---|
| **Product Name :** | **MYCOREN TABLETS<br>(Nystatin Tablets 500,000 I.U)** |

**Quantitative composition:**

| **Component and quality standard (and grade, if applicable)** | **Function** | **Strength (label claim)** | | | |
|---|---|---|---|---|---|
| | | Each sugar coated tablet contains Nystatin 500,000 I.U | | | |
| | | **Quantity in mg per tablet** | **%** | **Quantity in Kg Per 200,000 Tablets** | **%** |
| Contents of **MYCOREN TABLETS** | | | | | |
| Nystatin Ph. Eur, BP, USP | Active | 90.20 | 27.25 | 18.040 | 27.25 |
| Microcrystalline cellulose (MCC102) BP | Diluents | 100.00 | 30.21 | 20.000 | 30.21 |
| Sodium starch glycollate BP | Disintegrant | 3.00 | 0.91 | 0.600 | 0.91 |
| Magnesium stearate BP | Lubricant | 3.00 | 0.91 | 0.600 | 0.91 |
| Hydroxy propyl methyl cellulose USP | Polymer | 2.40 | 0.73 | 0.480 | 0.73 |
| Isopropyl alcohol BP* | Solvent | 6 µL | NA | 1.200L | NA |
| Methylene chloride BP* | Solvent | 10 µL | NA | 2.000L | NA |
| Maize starch BP | Dusting Powder | 2.500 | 0.76 | 0.500 | 0.76 |
| Purified Talc BP | Dusting Powder | 5.000 | 1.51 | 1.000 | 1.51 |
| Calcium Carbonate BP | Dusting Powder | 10.000 | 3.02 | 2.000 | 3.02 |
| Gum Acacia BP | Sub Coating | 3.000 | 0.91 | 0.600 | 0.91 |
| Gelatin BP | Sub Coating | 0.600 | 0.18 | 0.120 | 0.18 |
| Purified Talc BP | Sub Coating | 12.000 | 3.63 | 2.400 | 3.63 |
| Sucrose BP | Sub Coating | 60.000 | 18.13 | 12.000 | 18.13 |
| Titanium dioxide BP | Pigment | 0.900 | 0.27 | 0.180 | 0.27 |
| Sucrose BP | Colour Coat | 36.000 | 10.88 | 7.200 | 10.88 |
| Colour chocolate Brown IH | Pigment | 0.42 | 0.13 | 0.084 | 0.13 |
| Novoglow IH | Polishing | 2.50 | 0.60 | 0.500 | 0.60 |
| Isopropyl alcohol BP* | Solvent | 6 µL | NA | 1.200L | NA |
| Methylene chloride BP* | Solvent | 10 µL | NA | 2.000L | NA |
| Total | NA | **331.00** | **100.00** | **66.200** | **100.0** |

*Does not appeared on final product

Core tablet weight 196.2mg, coated tablet weight 313.0mg

**3. Pharmaceutical form:** tablets

**4. Clinical particular's:**

**4.1 Therapeutic indication:**

Mycoren is indicated for the treatment of mucocutaneous mycotic infections (Candidiasis) of the mouth and the alimentary tract, caused by Candida (Monilia) albicans and other species candida.

**4.2 Posology and method of administration:**

**Adults including the elderly:**

The recommended dose of mycoren should be taken 4 to 5 times daily, for as long as 14 days, if necessary. The dosage regimen should be continued for atleast 48 hours after the complete disappearance of symptoms. To treat the infected mucosa in the esophagus or the posterior pharnx.
Usual dosage - 500,000 to 1 million units (1 to 2 tablets or capsules) three times daily. Treatment should generally be continued for at least 48 hours after clinical cure to prevent a relapse.

**Method of Administration:** Oral route.

**4.3 Contraindication:**

Hypersensitivity to Nystatin.

**4.4 Special warning and precaution for use:**

Should a hypersensitivity reaction occur, administration of the drug should be immediately withdrawn and appropriate measures taken.

**4.5 Interactions with other medicinal products and other forms of interactions:**

Not known

**Additional information on special populations:**

Not Applicable

**Paediatric population:**

Not Applicable

**4.6 Fertility, pregnancy and lactation:**

Pregnancy

Animal reproductive studies have not been conducted with nystatin.

It is not known whether nystatin can cause foetal harm when administered to a pregnant woman or can affect reproductive capacity, however absorption of nystatin from the gastro-intestinal tract is negligible. Nystatin should be prescribed during pregnancy only if the potential benefits to be derived outweigh the potential risk to the foetus.

Breast-feeding

It is not known whether nystatin is excreted in human milk. Although gastrointestinal absorption is insignificant, caution should be exercised when nystatin is prescribed for a nursing woman.

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

None

**4.8 Undesirable effects:**

Nystatin is generally well tolerated by all age groups, even during prolonged use. If irritation or sensitisation develops, treatment should be discontinued. Nausea has been reported occasionally during therapy.

Large oral doses of Nystatin have occasionally produced diarrhoea, gastrointestinal distress, nausea and vomiting. Rash, including urticaria, has been reported rarely. Steven-Johnson Syndrome has been reported very rarely. Hypersensitivity and angioedema, including facial oedema have been reported.

**4.9 Overdose and Treatment:**

Since the absorption of nystatin from the gastro-intestinal tract is negligible, overdosage or accidental ingestion causes no systemic toxicity. Oral doses of nystatin in excess of 5 million units daily have caused nausea and gastrointestinal upset.5. Pharmacological Properties:

**5.1 Pharmacodynamic properties:**

Pharmacotherapeutic group: Antifungals for topical use, ATC code: D01AA01

Nystatin is an antifungal antibiotic active against a wide range of yeasts and yeast-like fungi, including *Candida albicans.*

**5.2 Pharmacokinetic properties:**

Absorption

Nystatin is formulated in oral and topical dosage forms and is not systemically absorbed from any of these preparations.

Gastrointestinal absorption of nystatin is insignificant.

Elimination

Most orally administered nystatin is passed unchanged in the stool.

**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.

**6. Pharmaceutical Particulars:**

**6.1 List of excipients**

Mycoren Tablets contains the following excipients:

Microcrystalline cellulose (MCC102) BP, Sodium starch glycollate BP, Colloidal silicon dioxide (Aerosil) USP, Magnesium stearate BP, Hydroxy propyl methyl cellulose USP, Isopropyl alcohol BP, Methylene chloride BP, Maize starch BP, Purified Talc BP, Calcium carbonate BP, Gum Acacia BP, Gelatin BP, Sucrose BP, Colour chocolate brown BP, Novoglow IH

**6.2 Incompatibilities**

None known

**6.3 Shelf life**

24 Months

**6.4 Special precaution for storage**

Store in cool & dry place. Below 30°C.

**6.5 Nature and contents of container**

10 Mycoren Tablets are packed in Aluminium/white PVC blister; such ten blisters are packed in a unit carton along with pack insert.
1000 tablets packed in polythene bag and contained in HDPE Container with leaflet.

**6.6 Special precautions for disposal**

No special precaution.

**7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES:**

**Marketing Authorization Holder:**
**Rene Industries Ltd**
Address : PO Box 6034, Plot No.680, Kamuli, Kireka, Kampala, Uganda.

**Manufactured by:**
**Rene Industries Ltd**
Address : PO Box 6034, Plot No.680, Kamuli, Kireka, Kampala, Uganda.

**8. MARKETING AUTHORISATION NUMBER:**
Not Applicable

**9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION:**
Not Applicable

**10. DATE OF REVISION OF THE TEXT:**
Not Applicable

**11. DOSIMETRY (IF APPLICABLE):**
Not Applicable

**12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE):**
Not Applicable