1.5 Product Information: MYCOREN SUSPENSION

1.5.1 Prescribing information (Summary of products characteristics):

1.6 1. Name of the Medicinal Product: MYCOREN SUSPENSION
Strength:
Each 1 ml contains Nystatin BP 100,000 I.U
Pharmaceutical form: Suspension

2. Qualitative and Quantitative composition:

Component and quality standard (and grade, if applicable)	**Function**	**Strength (label claim)**			
		Each 1 ml contains Nystatin BP 100,000 I.U			
		Quantity in mg per ml	**%**	**Quantity in Kg Per 500L**	**%**
Contents of **MYCOREN SUSPENSION**					
Nystatin	Active	25.000	2.5	12.500	2.5
Bronopol	Antimicrobial preservative	0.600	0.06	0.300	0.06
Sodium Saccharin	Sweetener	2.000	0.2	1.000	0.2
Carmellose Sodium	Viscosity enhancer	5.000	0.5	2.500	0.5
Propylene Glycol	Preservative	6.666	0.66	3.333	0.66
Disodium EDTA	Chelating agent	0.500	0.05	0.250	0.05
Sucrose	Sweetener	50.000	5.00	25.000	5.00
Tutti Frutti Flavour	Flavour	0.001332 ml	0.13	0.666 L	0.13
Purified Water	Solvent	Q.S.	Q.S. 1ml	Q.S.	Q.S. 500L
Total	NA	1.00 ml	100.00	500.00 L	100.00

3. Pharmaceutical form: Suspension

4. Clinical particular's:

4.1 Therapeutic indication:

Indications

The prevention and treatment of candidal infections of the oral cavity, oesophagus and intestinal tract.

The suspension also provides effective prophylaxis against oral candidosis in those born of mothers with vaginal candidosis.

4.2 Posology and method of administration:

Adults including the elderly:

Posology

Oral Candidiasis
Infants (1 month to 2 years)
1ml should be dropped into the mouth four times a day.
Children (≥ 2 years) and adults

For the treatment of denture sores, and oral infections in children (≥ 2 years) and adults caused by candidas albicans. 1ml of the suspension should be dropped into the mouth four times daily; it should be kept in contact with the affected areas as long as possible.
Intestinal candidiasis
Infants (1 month to 2 years)
1ml should be dropped into the mouth four times a day.
Adults

For the treatment of intestinal candidosis 5ml of the suspension should be dropped into the mouth four times daily.

Paediatric population (≥ 2 years)
1ml should be dropped into the mouth four times a day.
For prophylaxis a total daily dosage of 1 million units has been found to suppress the overgrowth of candidas albicans in patients receiving broad-spectrum antibiotic therapy.
For prophylaxis in the newborn the suggested dose is 1ml once daily.
The longer the suspension is kept in contact with the affected area in the mouth before swallowing, the greater will be its effect.
Administration should be continued for 48 hours after clinical cure to prevent relapse.
Older people
No specific dosage recommendations or precautions.

If signs and symptoms worsen or persist (beyond 14 days of treatment), the patient should be reevaluated, and alternate therapy considered.
Method of Administration: Oral route.

4.3 Contraindication:

Hypersensitivity to the active substance(s) or to any of the excipients.

4.4 Special warning and precaution for use:

Nystatin Oral Suspension BP contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. This should also be taken into account in patients with diabetes mellitus.

Nystatin Oral Suspension contains 0.3 mmol (or 1.3 mg) sodium per 1 ml dose. To be taken into consideration by patients on a controlled sodium diet.

Nystatin Oral Suspension contains sodium metabisulphite (E223) which may rarely cause severe hypersensitivity reactions and bronchospasm.

Nystatin Oral Suspension contains propyl p-hydroxybenzoate and methyl p-hydroxybenzoate which may cause allergic reactions (possibly delayed).

Nystatin oral preparations should not be used for treatment of systemic mycoses.

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 possible risks involved.

Breastfeeding

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 breast-feeding 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:

Nystatin is a mixture of antifungal polyenes produced by the growth of certain strains of Streptomyces noursei, or by any other means. It consists largely of Nystatin A1.

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

5.2 Pharmacokinetic properties:

Nystatin is a tetraene macrolide. There is no data available on the pharmacokinetics as it is not absorbed from the gastro-intestinal tract, skin or vagina and most of the use is topical. Microbial growth-inhibiting concentrations have been shown to be in the range 3-6mg/l.

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 Suspension contains the following excipients:

Bronopol, Sodium Saccharin, Carmellose Sodium, Propylene Glycol, Disodium EDTA, Sucrose, Tutti Frutti Flavour, Purified Water.

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

Amber glass bottles

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