

CTD MODULE 1
ADMINISTRATIVE INFORMATION AND
PRODUCT INFORMATION

Product Name :	MYCOREN V PESSARIES (Nystatin Pessaries 100,000 IU)
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1.5 Product Information: MYCOREN V PESSARIES

1.5.1 Prescribing information (Summary of products characteristics):

1. Name of the Medicinal Product: MYCOREN V PESSARIES

Strength:

Nystatin 100,000 I.U

Pharmaceutical form: Pessaries

2. Qualitative and Quantitative composition:

Qualitative composition:

Sr. No.	Ingredient	Specification	Uses
1.	Nystatin	Ph. Eur, BP, USP	Active
2.	Lactose	BP	Diluent
3.	Povidone K-30	BP	Binder
4.	Maize Starch	BP	Diluent
5.	Sodium Starch Glycollate	BP	Disintegrant
6.	Carbopol	BP	Stabilizer
7.	Glycerol Monolaurate	BP	Dispersing
8.	Maize Starch	BP	Binder
9.	Sodium Propyl Paraben	BP	Preservative
10.	Sodium Methyl Paraben	BP	Preservative
11.	Purified talc	BP	Guidant
12.	Magnesium stearate	BP	Lubricant
13.	Colloidal Silicon Dioxide	BP/USP	Glindant
14.	Microcrystalline cellulose PH 102	BP	Diluent & Disintegrant
15.	Sodium Starch Glycollate	BP	Disintegrant
16.	Sodium bicarbonate	BP	Disintegrant
17.	Maize Starch	BP	Diluent & Disintegrant

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Quantitative composition:

Component and quality standard (and grade, if applicable)	Function	Strength (label claim)			
		Nystatin 100,000 I.U			
		Quantity in mg per Pessary	%	Quantity in Kg Per 50,000 Pessaries	%
Contents of Mycoren V Pessaries					
Nystatin Ph. Eur, BP, USP	Active	20.000	2.00	1.000	2.00
Lactose BP	Diluent	460.000	46.00	23.000	46.00
Povidone K-30 BP	Binder	15.000	1.50	0.750	1.50
Maize Starch BP	Diluent	200.000	20.00	10.00	20.00
Sodium Starch Glycollate	Disintegrant	22.000	2.20	1.100	2.20
Carbopol BP	Stabilizer	5.000	0.50	0.250	0.50
Glycerol Monolaurate BP	Dispersing	12.000	1.20	0.600	1.20
Maize Starch BP	Binder	40.000	4.00	2.000	4.00
Sodium Propyl Paraben BP	Preservative	0.100	0.01	0.005	0.01
Sodium Methyl Paraben BP	Preservative	0.200	0.02	0.010	0.02
Purified talc BP	Glidant	8.000	0.80	0.400	0.80
Magnesium stearate BP	Lubricant	3.200	0.32	0.160	0.32
Colloidal Silicon Dioxide BP/USP	Glidant	1.500	0.15	0.075	0.15
Microcrystalline cellulose PH 102 BP	Diluent & Disintegrant	83.000	8.30	4.150	8.30
Sodium Starch Glycollate BP	Disintegrant	40.000	4.00	2.000	4.00
Sodium bicarbonate BP	Disintegrant	40.000	4.00	2.000	4.00
Maize Starch BP	Diluent & Disintegrant	50.000	5.00	2.500	5.00
Total	NA	1000.00	100%	50.000	100%

3. Pharmaceutical form: Pessaries

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4. Clinical particular's:

4.1 Therapeutic indication:

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

4.2 Posology and method of administration:

Adults including the elderly:

1 or 2 pessaries should be inserted high into the vagina for 14 consecutive nights or longer, regardless of any intervening menstrual period.

Children:

Not recommended.

Method of Administration: vaginal route.

4.3 Contraindication:

There are no known contraindications to use of Mycoren V Pessaries, except Hypersensitivity to any of the ingredients.

4.4 Special warning and precaution for use:

In pregnancy, care should be taken when using an applicator to prevent the possibility of mechanical trauma.

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:

In pregnancy, care should be taken when using the applicator provided to prevent the possibility of mechanical trauma.

CTD MODULE 1
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4.7 Effects on ability to drive and use machines:

None

4.8 Undesirable effects:

None stated

4.9 Overdose and Treatment:

None

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. Nystatin has both fungistatic and fungicidal effects.

5.2 Pharmacokinetic properties:

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

5.3 Preclinical safety data:

None stated.

6. Pharmaceutical Particulars:

6.1 List of excipients

Mycoren V Pessaries contains the following excipients:

Lactose, Povidone K30, Maize starch, Sodium starch glycollate, Carbopol, Glycerol Monolaurate, Sodium methyl paraben, Sodium propyl paraben, Purified Talc, Magnesium stearate, Colloidal silicon dioxide (Aerosil) and Sodium bicarbonate.

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.

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6.5 Nature and contents of container

15 pessaries are packed in Aluminium/PVC blister; such ten blisters are packed in a unit carton along with literature insert and applicator.

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