

**CTD MODULE 1**  
**ADMINISTRATIVE INFORMATION AND**  
**PRODUCT INFORMATION**

<b>Product Name :</b>	<b>RENESTEN-V PESSARIES</b> <b>(Clotrimazole Pessaries 100mg)</b>
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**1.5 Product Information: RENESTEN V PESSARIES**

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

**1. Name of the Medicinal Product: RENESTEN V PESSARIES**

**Strength:**

Clotrimazole 100mg

**Pharmaceutical form:** Pessaries

**2. Qualitative and Quantitative composition:**

**Qualitative composition:**

<b>Sr. No.</b>	<b>Ingredient</b>	<b>Specification</b>	<b>Uses</b>
1.	Clotrimazole	BP	Active
2.	Lactose Monohydrate	BP	Diluent
3.	Povidone K30	BP	Binder
4.	Sodium Lauryl Sulphate	BP	Surfactant
5.	Croscarmellose Sodium	BP	Disintegrant
6.	Colloidal Silicon Dioxide	BP/USP	Glidant
7.	Lactose Monohydrate	BP	Diluent
8.	Magnesium stearate	BP	Lubricant

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**Quantitative composition:**

Component and quality standard (and grade, if applicable)	Function	Strength (label claim)			
		Clotrimazole 100mg			
		Quantity in mg per Pessary	%	Quantity in Kg Per 100,000 Pessaries	%
<b>Contents of Renesten V Pessaries</b>					
Clotrimazole BP	Active	100.000	9.99	10.000	9.99
Lactose Monohydrate BP	Diluent	634.000	63.31	63.400	63.31
Povidone K30 BP	Binder	28.840	2.88	2.884	2.88
Sodium Luaryl Sulphate BP	Surfactant	2.340	0.23	0.234	0.23
Croscarmellose Sodium	Disintegrant	21.170	2.11	2.117	2.11
Colloidal Silicon Dioxide BP/USP	Glidant	9.500	0.95	0.950	0.95
Lactose Monohydrate BP	Diluent	202.150	20.18	20.215	20.18
Magnesium stearate BP	Lubricant	3.500	0.35	0.350	0.35
Total	NA	1000.00	100%	50.000	100%

**3. Pharmaceutical form:** Pessaries

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**4. Clinical particular's:**

**4.1 Therapeutic indication:**

For the treatment of vaginal thrush (candidiasis).

**4.2 Posology and method of administration:**

**Adults including the elderly:**

1 Pessary should be inserted high into the vagina for 6 consecutive nights, 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 Renesten V Pessaries, except Hypersensitivity to any of the ingredients.

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

As with other pessaries, this product may reduce the effectiveness of rubber contraceptives, such as condoms or diaphragms. Consequently, you should use alternative precautions for at least five days after using this product.

Do not use tampons, intravaginal douches, spermicides or other vaginal products while using this product. Avoid vaginal intercourse while you have thrush and during use of this product because your partner could become infected.

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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

Inform your doctor if you are taking tacrolimus or sirolimus (used to reduce the immune response to prevent rejection after an organ transplant).

**Additional information on special populations:**

Not Applicable

**Paediatric population:**

Not Applicable

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**4.6 Fertility, pregnancy and lactation:**

Do not use Clotrimazole Pessaries during pregnancy unless your doctor considers it essential. If used during pregnancy extra care should be taken when using the applicator to prevent the possibility of mechanical injury. Effects during breast-feeding are not known

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

The medication has no or negligible influence on the ability to drive or use machinery.

**4.8 Undesirable effects:**

As the listed undesirable effects are based on spontaneous reports, assigning accurate frequency of occurrence for each is not possible.

Immune system disorders:

allergic reaction (syncope, hypotension, dyspnea, urticaria, pruritus).

Reproductive system and breast disorders:

genital peeling, pruritus, rash, oedema, erythema, discomfort, burning, irritation, pelvic pain, vaginal haemorrhage.

Gastrointestinal disorders:

abdominal pain.

**4.9 Overdose and Treatment:**

No risk of acute intoxication is seen as it is unlikely to occur following a single vaginal or dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion. There is no specific antidote.

However, in the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

**5. Pharmacological Properties:**

**5.1 Pharmacodynamic properties:**

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane. Clotrimazole has a broad antimycotic spectrum of action *in vitro* and *in vivo*, which includes dermatophytes, yeasts, moulds, etc.

The mode of action of clotrimazole is primarily fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. *In vitro* activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.

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**5.2 Pharmacokinetic properties:**

Pharmacokinetic investigations after vaginal application have shown that only a small amount of clotrimazole (3 – 10% of the dose) is absorbed. Due to the rapid hepatic metabolism of absorbed clotrimazole into pharmacologically inactive metabolites the resulting peak plasma concentrations of clotrimazole after vaginal application of a 500 mg dose were less than 10 ng/ml, reflecting that clotrimazole applied intravaginally does not lead to measurable systemic effects or side effects

**5.3 Preclinical safety data:**

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity.

**6. Pharmaceutical Particulars:**

**6.1 List of excipients**

Renesten V Pessaries contains the following excipients:

Lactose, Povidone K30, Sodium lauryl sulphate, Croscarmellose Sodium, Magnesium stearate and Colloidal silicon dioxide (Aerosil).

**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**

6 Pessaries are packed in Aluminium/PVC blister; such ten blisters are packed in a unit carton along with literature insert.

**6.6 Special precautions for disposal**

No special precaution.

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**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