1.5 Product Information: RENECHLOR CAPSULES

1.5.1 Prescribing information (Summary of products characteristics):

1. Name of the Medicinal Product: RENECHLOR CAPSULES

Strength:
Each hard gelatin capsule contains Chloramphenicol BP 250mg
Pharmaceutical form: Capsules

2. Qualitative and Quantitative composition:
Qualitative composition and Quantitative composition:

Component and quality standard (and grade, if applicable)	**Function**	**Strength (label claim)**			
		Each hard gelatin capsule contains Chloramphenicol BP 250mg			
		Quantity in mg per capsule	**%**	**Quantity in Kg Per 1,000,000 C**	**%**
Contents of **RENECHLOR CAPSULES**					
Chloramphenicol	Active	250.000	73.36	250.000	73.36
Maize starch	Binder	68.000	19.96	68.000	19.96
Colloidal silicon dioxide	Glidant	1.500	0.44	1.500	0.44
Purified talc	Dusting powder	20.31	5.95	20.31	5.95
Magnesium stearate	Lubricant	1.000	0.29	1.000	0.29
EHG capsules (Renechlor capsules)	Vehicle	1 Unit	-	1,000,000 Nos.	-
Total	NA	340.81	100.00	340.81	100.00

3.Pharmaceutical form: Capsules

4. Clinical particular's:

4.1 Therapeutic indication:

– Alternative to first-line treatments of bubonic plague
– Typhoid fever if the strain is susceptible (recent drug susceptibility test)
– Completion treatment following parenteral therapy with chloramphenicol

4.2 Posology and method of administration:

Child from 1 year to less than 13 years: 12.5 mg/kg 3 to 4 times daily; the dose should be doubled in severe infection (max. 3 g daily)
– Child ≥ 13 years and adult: 1 g 3 to 4 times daily

Age	Weight	250 mg capsule
1 to < 4 years	10 to < 17 kg	1 cap x 3
4 to < 9 years	17 to < 30 kg	2 cap x 3
9 to < 13 years	30 to < 45 kg	3 cap x 3
≥ 13 years and adult	≥ 45 kg	4 cap x 3

Duration
– *Plague*: 10 days; *typhoid fever*: 7 days

4.3 Contraindication:

– Do not administer to children under 1 year.
– Do not administer to patients with:
• history of allergic reaction or bone marrow depression during a previous treatment with chloramphenicol;
• G6PD deficiency.
– May cause:
• dose-related haematological toxicity (bone marrow depression, anaemia, leucopenia, thrombocytopenia), allergic reactions. In these events, stop treatment immediately;
• gastrointestinal disturbances, peripheral and optic neuropathies.
– Reduce dosage in patients with hepatic or renal impairment.
– Avoid or monitor combination with potentially haematotoxic drugs (carbamazepine, co-trimoxazole, flucytocine, pyrimethamine, zidovudine, etc.).
– Pregnancy: CONTRA-INDICATED, except if vital, if there is no therapeutic alternative. If used during the 3rd trimester, risk of grey syndrome in the newborn infant (vomiting, hypothermia, blue-grey skin colour and cardiovascular depression).
– Breast-feeding: CONTRA-INDICATED

4.4 Special warning and precaution for use:
Not applicable

4.5 Interactions with other medicinal products and other forms of interactions:
Not applicable

4.6 Fertility, pregnancy and lactation:
Not applicable

4.7 Effects on ability to drive and use machines:
Not applicable

4.8 Undesirable effects:
Not applicable

4.9 Overdose and Treatment:
Not applicable

5. Pharmacological Properties:

5.1 Pharmacodynamic properties:

Chloramphenicol is bacteriostatic but may be bactericidal in high concentrations or when used against highly susceptible organisms. Chloramphenicol stops bacterial growth by binding to the bacterial ribosome (blocking peptidyl transferase) and inhibiting protein synthesis.

5.2 Pharmacokinetic properties:

Most of a chloramphenicol dose is metabolised by the liver to inactive products, the chief metabolite being a glucuronide conjugate; only 5 to 15% of chloramphenicol is excreted unchanged in the urine. The elimination half-life is approximately 4 hours.

5.3 Preclinical safety data:

Not available

6. Pharmaceutical Particulars:

6.1 List of excipients

Renechlor Capsules contains the following excipients:
Maize starch, Colloidal silicon dioxide, Purified talc, Magnesium stearate.

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precaution for storage

Store in cool & dry place. Below 25°C.

6.5 Nature and contents of container

Alu/PVC blister

6.6Special 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