

## **Summary of products characteristics (SmPC):**

### **1. Name of the Medicinal Product: RENECHLOR CAPSULES**

### **2. Qualitative and Quantitative composition:**

Each hard gelatin capsule contains Chloramphenicol BP 250mg. For the full list of excipients, See section 6.1

### **3. Pharmaceutical form: Capsules**

Off white coloured size '2' capsules with "Chloro" and "250" imprinted on body and cap respectively in black ink containing off white colour powder.

### **4. Clinical particular's:**

#### **4.1 Therapeutic indication:**

Renechlor capsules contain chloramphenicol which is an antibiotic for specific uses.

They are used for treatment of typhoid fever and other dangerous infections where other antibiotics are not effective.

#### **4.2 Posology and method of administration:**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the capsules whole with a drink of water.

#### **Adults and elderly**

The usual dose is 500 mg (2 capsules) every 6 hours or 50 mg per kg body weight daily in divided doses.

**Blood tests** may be carried out to check the level of chloramphenicol in your body and to make sure your blood is functioning properly, as chloramphenicol can damage blood cells.

#### **Use in children**

This medicine is not suitable for children.

#### **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, cotrimoxazole, 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:**

Talk to your doctor or pharmacist before taking Renechlor capsules

- if you have liver or kidney problems
- if you are elderly
- if you are taking any of the medicines listed in the next section “Other medicines and Renechlor capsules”.

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

Not applicable

#### **4.6 Fertility, pregnancy and lactation:**

Do not take Renechlor capsules if you are pregnant, planning to become pregnant or breast-feeding as they may harm the baby.

Chloramphenicol may cause a condition called Grey Baby Syndrome, where the baby’s skin appears grey and the baby is listless and weak. This may be fatal and requires immediate medical attention.

Ask your doctor, pharmacist or nurse for advice before taking any medicine.

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

Renechlor capsules have no or negligible influence on the ability to drive and use machines.

#### **4.8 Undesirable effects:**

Not applicable

#### **4.9 Overdose and Treatment:**

Not applicable

## **5. Pharmacological Properties:**

### **5.1 Pharmacodynamic properties:**

Pharmacotherapeutic group: Antibiotic, ATC Code: J01BA01

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**

Do not store above 30°C. Protect from light. Keep out of reach of children.

### **6.5 Nature and contents of container**

Aluminium /PVC blister strip of 10 capsules and 10 of such blister strips are packed in a unit box with pack insert.

### **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