

CTD MODULE 1
ADMINISTRATIVE INFORMATION AND
PRODUCT INFORMATION

Product Name :	RENECHLOR CAPSULES (Chloramphenicol BP 250mg)
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Pack Insert:

RENECHLOR

COMPOSITION

Capsules:
Each Capsule contains
Chloramphenicol BP 250mg

Suspension
Each 5ml contains
Chloramphenicol BP 125mg (as palmitate)

CLINICAL PHARMACOLOGY
Chloramphenicol exerts mainly bacteriostatic effect on a wide range of gram-negative and gram-positive bacteria. The mode of action is through interference or inhibition of protein synthesis in intact cells and in cell-free systems.

INDICATIONS
Chloramphenicol must be used only in those serious infections for which less potentially dangerous drugs are ineffective or contraindicated.

a) *Salmonella* species
b) H-influenza, specifically meningial infections
c) Rickettsia
d) Lymphogranuloma-psittacosis group
e) Various gram-negative bacteria causing bacteremia, meningitis or other gram-negative infections
f) In the treatment of typhoid fever

DOSAGE AND ADMINISTRATION

Adults:
Adults should receive 50mg/kg/day in divided doses at 6-hour intervals. Adults with impairment of hepatic or renal function or both may have reduced ability to metabolize and excrete the drug. In instances of impaired metabolic processes, dosages should be adjusted accordingly.

Children:
Dosage of 50 mg/kg/day divided into 4 doses at 6-hour intervals.

SIDE EFFECTS
The most serious adverse effect of Chloramphenicol is bone marrow depression. Serious and fatal blood dyscrasias (aplastic anaemia, hypoplastic anemia, thrombocytopenia and granulocytopenia) are known to occur after the administration of Chloramphenicol. Nausea, vomiting, glossitis and stomatitis, diarrhea and enterocolitis may occur in low incidences. Headache, mild depression, mental confusion and delirium have been described in patients receiving Chloramphenicol.

PRECAUTIONS
Excessive blood levels may result from administration of the recommended dose to patients with impaired liver kidney function. Since Chloramphenicol readily crosses the placental barrier, caution in use of the drug is particularly important during pregnancy at term and during labor because of potential toxic effects on the fetus (gray syndrome). Precaution should be used in therapy during lactation because of the possibility of toxic effects on the nursing infant.


CONTRA-INDICATIONS
Chloramphenicol is contra indicated in individuals with a history of previous hypersensitivity and/or toxic reactions to it.

PRESENTATION

Capsules
Jar of 1000 capsules
Blister pack of 10 X 10 Capsules,
Suspension 100ml bottles

STORAGE
Store in the cool dry place below 30°C.
Protect from light, Keep out of reach of children.

MANUFACTURED BY:-
RENE INDUSTRIES LIMITED
Plot 680, Kamul, Kireka,
P. O. Box 6034, Kampala, Uganda


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