SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CHLORAKRIS CAPSULES (CHLORAMPHENICOL CAPSULE 250 mg)

is an oral Capsule Composition:

Each Capsule contains:

Chloramphenicol BP 250mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Excipients: Maize Starch, Microcrystalline Cellulose, Dibasic Calcium Phosphate, Magnesium Stearate, Purified Talc & Colloidal Silicon Dioxide (Aerosil).

For a full list of excipients, see section 6.1

3. Pharmaceutical Form

Oral Capsule

CHLORAKRIS is an opaque white to off white coloured cap and body printed with "CHLORAKRIS" on cap and 250mg on the body, size "1" hard gelatin capsules containing almost off white colour free flowing powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications:

CHLORAKRIS Capsule is indicated for: treatment of typhoid fever and other dangerous infections where other antibiotics are not effective.

4.2 Posology and method of administration:

Posology

Adults and children over 12 years: 500 mg (2 capsules) every 6 hours

Method of Administration

For oral administration.

4.3 Contraindications

Do not take CHLORAKRIS capsules if you are allergic to chloramphenicol or any of the other ingredients. if you have recently been vaccinated, pregnant or are breast-feeding, if you have porphyria (a metabolism disorder which causes abdominal pains and mental disorder) have a minor infection, are taking medicines that may suppress your bone marrow.

4.4 Special warnings and precautions for use Take special care with CHLORAKRIS capsules Before taking the capsules, tell your doctor if you:

- have liver or kidney problems
- are elderly
- Taking other medicines

4.5 Interaction with other medicinal products and other forms of interaction:

Administration of chloramphenicol concomitantly with bone marrow depressant drugs is contraindicated, although concerns over aplastic anaemia associated with ocular chloramphenicol have largely been discounted.

Chloramphenicol is a potent inhibitor of the cytochrome P450 isoforms CYP2C19 and CYP3A4 in the liver. Inhibition of CYP2C19 causes decreased metabolism and therefore increased levels of, for example, antidepressants, antiepileptics, proton-pump inhibitors, and anticoagulants if they are given concomitantly. Inhibition of CYP3A4 causes increased levels of, for example, calcium channel blockers, immunosuppressants, chemotherapeutic drugs, benzodiazepines, azole antifungals, tricyclic antidepressants, macrolide antibiotics, SSRIs, statins, cardiac antiarrhythmics, antivirals, anticoagulants, and PDE5 inhibitors.

4.6 Pregnancy and Lactation

DO NOT take CHLORAKRIS 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 for advice before taking any medicine.

4.7 Effects on the ability to drive and use machines

CHLORAKRIS capsules are unlikely to affect your ability to operate machinery or to drive.

4.8 Undesirable effects:

CHLORAKRIS Side effects include; Anemia, Dark colored urine, Sore throat and fever, Unusual bleeding or bruising, Difficulty in breathing, Headache, Nausea and Vomiting, Burning, numbness, tingling in the arms and feet, Swelling of face, lips, eyelids, tongue, hands and feet, Depression.

4.9 Overdose

In case of any overdose, treatment will be symptomatic

5. PHARMACOLOGICAL PARTICULARS

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Antibiotics **ATC Code:** J01BA01

Mechanism of action:

Chloramphenicol is a bacteriostatic by inhibiting protein synthesis. It prevents protein chain elongation by inhibiting the peptidyl transferase activity of the bacterial ribosome. It specifically binds to A2451 and A2452 residues in the 23S rRNA of the 50S ribosomal subunit, preventing peptide bond formation. Chloramphenicol directly interferes with substrate binding in the ribosome, as compared to macrolides, which sterically block the progression of the growing peptide.

5.2 Pharmacokinetic properties

Absorption

Rapidly and completely absorbed from gastrointestinal tract following oral administration (bioavailability 80%). Well absorbed following intramuscular administration (bioavailability 70%). Intraocular and some systemic absorption also occurs after topical application to the eye.

Distribution

Distributed widely to most body tissues and fluids, including CSF, liver, and kidneys; it readily crosses the placental barrier. About 50% to 60% of drug binds to plasma proteins.

Elimination

About 8% to 12% of dose is excreted by the kidneys as unchanged drug; the remainder is excreted as inactive metabolites. Plasma half-life ranges from about 1 1/2 to 4 1/2 hours in adults with normal hepatic and renal function. Plasma half-life of parent drug is prolonged in patients with hepatic dysfunction. Peritoneal hemodialysis doesn't remove significant drug amounts. Plasma chloramphenicol levels may be elevated in patients with renal impairment after I.V. chloramphenicol administration.

5.3 Pre-clinical Safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients Maize Starch, Microcrystalline Cellulose, Dibasic Calcium Phosphate, Magnesium Stearate, Purified Talc & Colloidal Silicon Dioxide (Aerosil).

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months.

6.4 Special Precautions for storage

Store below 30^{o}C, protect from heat light.
Keep out of reach and sight of children.

6.5 Nature and contents of container

Alu-PVC blister of 10 Capsules, such 10 blisters are packed in carton along with the pack insert

6.6 Special precautions for disposal and other handling

No special requirements.

7. **Manufactured By**

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