SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Chloram-SSP 250 (Chloramphenicole capsule BP 250mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard gelatin capsule contains 250 mg of chloramphenicol.

For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

White, blue gelatine capsules.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Typhoid fever and life-threatening infections, particularly those caused by Haemophilus influenzae where other antibiotics will not suffice.

4.2. Posology and method of administration

Posology

Adults and elderly

The normal dose is 50 mg/kg body weight daily in 4 divided doses. For severe infections (meningitis, septicaemia) this dose may be doubled initially, but it must be reduced as soon as clinically practical.

Paediatric population

The safety and efficacy of Chloramphenicol Capsules BP 250 mg have not yet been established in children.

Method of administration

Oral; the Capsules should be swallowed with a drink of water.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Chloramphenicol is contra-indicated in prophylaxis or treatment of minor infections; during active immunisation; and in porphyria patients.

Chloramphenicol is contra-indicated in patients taking drugs liable to depress bone marrow function.

Chloramphenicol must not be used in breast-feeding mothers and during pregnancy or labour, due to a risk of foetal/ infant damage (Gray Baby syndrome).

4.4. Special warnings and precautions for use

Chloramphenicol should only be used if other treatments are ineffective and its use should always be carefully monitored.

Dose reduction and plasma level monitoring may be required in patients with hepatic or renal impairment; in the elderly; and in patients concurrently treated with interacting drugs.

Periodic blood testing should be conducted during prolonged or repeated treatment. Chloramphenicol should be discontinued if a significant detrimental effect is seen.

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

Warfarin, phenytoin, sulphonylureas and tolbutamide

Chloramphenicol prolongs the elimination, increasing the blood levels, of drugs including warfarin, phenytoin, sulphonylureas, tolbutamide.

Anticonvulsants and anticoagulants

Doses of anticonvulsants and anticoagulants may need to be adjusted if given concurrently.

Penicillins and rifampicin

Complex effects (including reduced / increased plasma levels) requiring monitoring of chloramphenicol plasma levels have been reported with co-administration of penicillins and rifampicin.

Paracetamol

Concurrent administration of paracetamol should be avoided as this prolongs chloramphenicol half-life.

Calcineurin Inhibitors (CNIs) Ciclosporin and Tacrolimus

Treatment with chloramphenicol possibly increases the plasma levels of the CNIs ciclosporin and tacrolimus.

Barbiturates

The metabolism of chloramphenicol is accelerated by barbiturates, such as phenobarbitone, leading to reduced plasma concentrations. There is a possible decrease in the metabolism of phenobarbitone with concomitant chloramphenicol administration.

Oestrogens

There is a small risk that chloramphenicol may reduce the contraceptive effect of oestrogens.

Hydroxocobalamin

Chloramphenicol reduces the response to hydroxocobalamin.

Drugs causing agranulocytosis

Chloramphenicol is contra-indicated in patients taking drugs liable to suppress bone marrow function (see section 4.3). These include:

- Carbamazapine
- Sulphonamides
- Phenylbutazone
- Penicillamine
- Cytotoxic agents
- Some antipsychotics, including clozapine and particularly depot antipsychotics
- Procainamide
- Nucleoside reverse transcriptase inhibitors
- Propylthiouracil

4.6. Fertility, pregnancy and lactation

Pregnancy

Chloramphenicol crosses the placenta. Therefore chloramphenicol is contraindicated during pregnancy.

Breast-feeding

Chloramphenicol is excreted in breast milk. Therefore chloramphenicol is contraindicated during breast-feeding.

Fertility

No human data on the effects of chloramphenicol on fertility is available.

4.7. Effects on ability to drive and use machines

Chloramphenicol Capsules BP 250 mg have no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as follows: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/100,000), not known (cannot be estimated from the available data).

Blood and lymphatic disorders	
Rare:	(i) A reversible dose related bone marrow depression. (ii) An irreversible aplastic anaemia
Not known:	Increase in bleeding time.
Immune system disorders	
Not known:	Hypersensitivity reactions including allergic skin reactions.
Eye disorders	
Not known:	Optic neuritis leading to blindness.
Ear and labyrinth disorders	
Not known:	Ototoxicity.
Vascular disorders	
Not known:	Acidotic cardiovascular collapse.
Gastrointestinal disorders	
Not known:	Nausea, vomiting, glossitis, stomatitis, diarrhoea, enterocolitis.
Pregnancy, puerperium and perinatal conditions	
Not known:	"Gray" syndrome, particularly in the newborn, which appears to be related to excessively high plasma levels. The Gray baby syndrome consists of abdominal distension, pallid cyanosis, vomiting, progressing to vasomotor collapse, irregular respiration and death within a few hours of onset of symptoms. (These symptoms are thought to be dose related and rapid clearance of chloramphenicol has been associated with recovery).

4.9. Overdose

Where adverse effects show signs of developing administration must be stopped immediately

and treatment is mainly supportive. If an allergy develops, oral antihistamines may be used. In severe overdosage e.g. Gray Baby Syndrome, there is a need for a rapid reduction in plasma levels and it has been reported that resin haemoperfusion (XAD-4) substantially increases Chloramphenicol clearance.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterials for systemic use, amphenicols, ATC Code: J 01 BA 01.

Chloramphenicol is a broad-spectrum antibiotic acting by interfering with bacterial protein synthesis. The most important action on the body tissue is the adverse one of bone marrow depression. There is significant plasma protein binding and the drug is largely inactivated in the liver.

5.2. Pharmacokinetic properties

Chloramphenicol is readily and rapidly absorbed from the G.I. tract. Particle size may affect rate of absorption, but will not affect total absorption. Significant serum levels observable 30 minutes after ingestion and half life may be 2–5 hours.

Chloramphenicol is widely distributed in body tissues and fluids. It is found in Cerebro-spinal fluid. It crosses the placental barrier and diffuses into breast milk.

There is significant plasma protein binding (up to 60%). Excretion is mainly in the urine and largely inactivated in the live.

5.3. Preclinical safety data

Not available.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Maize Starch- BP

Carboxy methyl starch-BP

Silicon Dioxide- BP

Magnesium Stearate- BP

Hard gelatin capsule size 1

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years

6.4. Special precautions for storage

Store below 30°C, protect from light and moisture.

6.5. Nature and contents of container

Clear and colourless PVC /Aluminium blisters containing capsules. 10 capsules per blister

and 5 blisters in box (10x5) or 10capsules per blister and 10 blisters in box (10x10).

6.6. Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

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8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

07519/08044/NMR/2019

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/07/2022

10. DATE OF REVISION OF THE TEXT

07/07/2023