CHLODOT

Chloramphenicol Sodium Succinate Injection Veterinary Use

Description

Chloramphenicol Sodium Succinate Injection is a sterile, lyophilized powder designed for **parenteral administration in animals**. It contains **Chloramphenicol Sodium Succinate**, a water-soluble prodrug of Chloramphenicol, a broad-spectrum antibiotic effective against a wide range of Gram-positive and Gram-negative bacteria as well as some anaerobes.

Upon administration, the succinate ester is rapidly hydrolysed in the body to active Chloramphenicol. It is commonly used in veterinary medicine for infections where oral administration is impractical or ineffective.

Specifications

- **Dosage Form:** Sterile lyophilized powder for injection
- **Appearance (Dry Powder):** White to off-white crystalline powder
- **Appearance (After Reconstitution):** Clear, colourless to pale yellow solution
- **pH (Reconstituted Solution):** Approximately 5.5 to 7.0
- **Sterility:** Complies with Indian Pharmacopoeia (I.P.) and veterinary standards
- **Assay:** 95% – 105% of labelled content
- **Moisture Content:** Within specified limits
- **Container:** Type I glass vial with rubber stopper and aluminium seal

Composition

Each vial contains:

- **Chloramphenicol Sodium Succinate I.P.** equivalent to **Chloramphenicol** – 3 gm or 4 gm
- **Excipients:** Suitable pharmacopeial-grade additives
- **Sterile Water for Injection:** Provided free for reconstitution

Pharmacological Category

- **Therapeutic Class:** Broad-spectrum antibiotic
- **Drug Class:** Amphenicol antibiotic

- **Mechanism of Action:**
  Chloramphenicol inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit, preventing peptide bond formation, resulting in bacteriostatic or bactericidal effects depending on the organism and concentration.

🐾 Indications (Veterinary Use)

Used in the treatment of susceptible bacterial infections in animals such as:

- Respiratory tract infections
- Septicaemia and systemic infections
- Soft tissue and wound infections
- Mastitis and metritis
- Gastrointestinal infections
- Other infections caused by susceptible organisms where other antibiotics are contraindicated or ineffective

💉 Dosage and Route of Administration

Route:

- Intravenous (I.V.) or Intramuscular (I.M.) injection

Dosage:

- 25 to 50 mg/kg body weight, once or twice daily depending on severity and species
- Duration: Typically 5 to 7 days, adjust per clinical response

Note:

- Reconstitute immediately before use with sterile water supplied.
- Administer slowly by intravenous injection to avoid adverse reactions.

🧴 Dosage Form and Presentation

- Sterile dry powder for injection
- Available in vials containing 3 gm or 4 gm of Chloramphenicol Sodium Succinate equivalent
- Each pack contains sterile water for injection for reconstitution

🌟 Key Advantages

- Broad-spectrum antimicrobial action
- Rapid conversion to active form upon injection
- Effective against a variety of aerobic and anaerobic bacteria
- Suitable for use when oral therapy is not possible
- Useful in mixed infections

⚠️ Adverse Effects

- Local pain or irritation at injection site
- Hypersensitivity reactions (rare) including anaphylaxis
- Bone marrow suppression (dose-dependent, usually reversible)
- Gastrointestinal disturbances
- Potential for fatal aplastic anaemia in humans; handle with care to avoid exposure

❗ Precautions and Contraindications

- Contraindicated in animals with known hypersensitivity to Chloramphenicol
- Avoid use in animals with pre-existing bone marrow disorders
- Use cautiously in neonates and debilitated animals
- Not recommended in food-producing animals in some countries due to human safety concerns; always adhere to local regulatory guidelines
- Avoid extravasation of the injection as it can cause local tissue damage
- Follow strict withdrawal periods

⏳ Withdrawal Period

- **Meat:** Minimum 28 days (varies with local regulations)
- **Milk:** Minimum 7 days (if applicable and per regulation)
- Observe all regulatory withdrawal periods before using animal products for human consumption.

🧊 Storage and Handling

- Store below 25°C in a dry, dark place
- Protect from moisture and light
- Do not freeze
- Use immediately after reconstitution
- Dispose of unused solution responsibly
- Handle with gloves to avoid human exposure

💊 Schedule / Regulatory Classification

- Prescription-only veterinary medicine
- Regulated under Schedule H or local equivalents
- Strict veterinary supervision required
- Not for human use

📦 HS Code / HSN Code

- **HS Code (International):** 3004.90 – Other medicaments for veterinary use
- **HSN Code (India):** 3004.90.99 – Veterinary antibiotics and related formulations

📌 Special Instructions

- Use strictly under veterinary prescription
- Avoid off-label use especially in food-producing animals
- Ensure accurate dosing based on animal weight
- Monitor for signs of adverse reactions during therapy
- Complete the full course of treatment to prevent resistance

❓ Frequently Asked Questions (FAQs)

Q1: What is Chloramphenicol Sodium Succinate?
A: It is a water-soluble prodrug of Chloramphenicol used for injectable therapy in animals.

Q2: Why is it preferred over oral Chloramphenicol in some cases?
A: Injectable form ensures rapid, controlled dosing and is useful when oral administration is not feasible.

Q3: Can this be used in food-producing animals?
A: Use is restricted or banned in many countries due to risk of human aplastic anaemia; follow local regulatory guidelines strictly.

Q4: What are the main side effects?
A: Bone marrow suppression and hypersensitivity; monitor animals carefully.

Q5: How should the injection be administered?
A: Intravenously or intramuscularly, preferably slowly to reduce adverse reactions.

Q6: Can reconstituted solution be stored?
A: No, use immediately after reconstitution to maintain sterility and potency.