

For the use only of registered medical practitioner or a hospital or a laboratory

Rx

Chloramphenicol Sodium Succinate Injection IP

Nicol 1g Injection

COMPOSITION :

Each vial contains :
Chloramphenicol Sodium
Succinate IP (Sterile)
Eq. to Chloramphenicol 1000 mg

CLINICAL PHARMACOLOGY

This medicine contains chloramphenicol sodium succinate, which is an antibiotic used to treat severe infections such as typhoid and meningitis and should only be used when other antibiotics do not help or are unsuitable. It is also used when oral chloramphenicol cannot be used or when higher amounts of the medicine is needed in the blood. Chloramphenicol prevents bacteria making an essential nutrient required for growth and multiplication. In time, the number of bacteria are reduced and the infection is controlled, so that treatment can be continued using a more gentle antibiotic.

INDICATIONS AND USAGE:

Chloramphenicol Injection should not be used for trivial infections due to the possibility of severe blood dyscrasias which may prove fatal. Chloramphenicol Injection is indicated for typhoid, meningitis caused by H. influenzae and other serious infections caused by bacteria susceptible to chloramphenicol. It is also indicated wherever chloramphenicol is deemed the antibiotic of choice and oral administration is not possible, or where higher than usual blood concentrations are required.

DOSAGE & ADMINISTRATION:

To be given by intravenous injection or infusion or by intramuscular injection. In order to ensure rapid attainment of high blood levels, Chloramphenicol Injection is best administered intravenously. Where this is not possible, intramuscular administration may be used, although absorption may be slow and unpredictable. The use of the intramuscular route should be restricted to those patients where parenteral administration is considered most appropriate but intravenous use is impossible or impractical. Intravenous administration should be as a 10% (100 mg/mL) solution to be injected over at least a one-minute interval, or in a larger volume of fluid, by slow intravenous infusion after reconstitution. The same 10% (100 mg/mL) solution can also be administered intra-muscularly, if necessary.

WARNINGS & PRECAUTIONS:

- If you have a history of kidney or liver disease.
- If you are already taking any other medicines which may also cause bone marrow depression.
- If you have a cold, viral influenza, throat infection and before using this medicine to prevent bacterial infections.
- If you have recently been or are about to be vaccinated.

DRUG INTERACTIONS:

Chloramphenicol has been shown to interact with, and enhance the effects of coumarin anticoagulants, some hypoglycaemic agents (e.g. tolbutamide) and phenytoin. When given concurrently, a dose reduction of these agents may be necessary. Plasma concentrations of chloramphenicol may be reduced with concomitant usage of phenobarbital and rifampicin.

PREGNANCY AND BREAST-FEEDING

Do not use Chloramphenicol Injection if you are pregnant, or are breast-feeding.

ADVERSE REACTIONS

- Severe allergic reaction e.g. red raised areas on your skin which may look like spots or be several

inches across, which cause itchiness.

- Grey Syndrome – usually in new-born or premature infants, where the skin appears grey, and the infant is listless and weak.
- White blood cell counts (which fight infection) can also drop, increasing the chance of infections, bruising and fever.
- Anaemia (a low red blood cell count) that can leave you feeling tired and lethargic.

Other side effects may occur, but, the frequency cannot be estimated from the available data:

- Dry mouth.
- Nausea (feeling sick), vomiting (being sick) and diarrhoea.
- Headache.
- Depression.
- Inflammation or damage to the nerves causing numbness, tingling, pain or muscle weakness.
- Blurring, inflammation or temporary loss of vision.
- Chloramphenicol may slow down development of immunity, and you may develop infections more frequently, which are difficult to fight off.

OVERDOSAGE:

Levels exceeding 25 mcg/ml are frequently considered toxic.

Symptoms

Chloramphenicol toxicity can be evidenced by serious haemopoietic effects such as aplastic anaemia, thrombocytopenia, leucopenia, as well as increasing serum iron levels, nausea, vomiting and diarrhoea.

Management

In the case of serious overdosage, charcoal haemoperfusion may be effective in removing chloramphenicol from plasma.

Exchange transfusion is of questionable value following massive overdosage, especially in neonates and infants.

Shelf life: 2 Years.

STORAGE

Store below 25°C. Protect from light & moisture.

Medicine: Keep out of the reach of children.

PRESENTATION :

1 vial with SWFI IP packed in a inner carton and such 20 inner cartons packed in a outer carton.

Marketed by:



American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)

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