

Module I Administrative Information

Product Name: Chlomalol (Chloramphenicol Capsules 250mg)

1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Enclosed.

Module I Administrative Information

Product Name: Chlomalcol (Chloramphenicol Capsules 250mg)

Summary Product Characteristics

1. Name of the proprietary product: ---

Name of the nonproprietary International Product: Chlomalcol (Chloramphenicol Capsule)

Route of Administration: Oral

2. Qualitative and Quantitative composition:

Sr. No.	Ingredient	Specification	Qty / Vial	Reason on inclusion
1.	Chloramphenicol Capsules 250mg	USP	*250 mg	Active

Where, USP = United States Pharmacopoeia.

*Value of Target weight will vary accordingly to the Water Content and Assay of Ceftriaxone sodium.

Module I Administrative Information

Product Name: Chlomagol (Chloramphenicol Capsules 250mg)

3. Pharmaceutical Form: Capsule

4. Clinical Particulars:

4.1 Therapeutic Indications:

Chloramphenicol is used in the treatment of infections caused by bacteria. It works by killing bacteria or preventing their growth.

Chloramphenicol is used to treat serious infections in different parts of the body. It is sometimes given with other antibiotics. However, chloramphenicol should not be used for colds, flu, other virus infections, sore throats or other minor infections, or to prevent infections.

Chloramphenicol should only be used for serious infections in which other medicines do not work. This medicine may cause some serious side effects, including blood problems and eye problems. Symptoms of the blood problems include pale skin, sore throat and fever, unusual bleeding or bruising, and unusual tiredness or weakness. You and your doctor should talk about the good this medicine will do as well as the risks of taking it .

Chloramphenicol is available only with your doctor's prescription.

4.2 Posology and method of administration:

Dosages of Chloramphenicol:

Injectable solution

1,000 mg/vial

Dosage Considerations – Should be Given as Follows:

Serious Infections Caused by Susceptible Strains

Adults:

50 mg/kg/day intravenously divided every 6 hours; in exceptional cases, patients with moderately resistant organisms or severe infections may require increased dosage up to 100 mg/kg/day; decrease these high doses as soon as possible

Systemic Infections

Pediatric:

Infants and children: As in adults; when adequate cerebrospinal fluid concentrations desired, may require up to 100 mg/kg/day; however, should reduce dose to 50 mg/kg/day as soon as possible

Module I Administrative Information

Product Name: Chlomalcol (Chloramphenicol Capsules 250mg)

- Infants and children with suspected immature metabolic functions: 25 mg/kg/day divided every 6 hours will usually produce therapeutic concentrations of the drug in the blood

Neonates (Infants younger than 28 days)

Pediatric:

- Loading dose (LdD): 20 mg/kg intravenously once; give maintenance dose 12 hours after loading dose

Maintenance Dose

- Infants younger than 7 days old: 25 mg/kg/day intravenously every 24 hours
- Infants over 7 days old, less than 2000 g: 25 mg/kg/day intravenously every 24 hours
- Infants over 7 days old, over 2000 g: 50 mg/kg/day intravenously every 12 hours

Other Information

Pediatric:

- Peaks 10-20 mg/l, troughs 5-10 mg/l

Other Indications and Uses

Adults:

- Use only as alternative for treatment of meningitis, typhoid, or rickettsial infection

4.3 Contraindications

The following conditions are contraindicated with this drug.

1. Conditions:

- hereditary liver metabolism disorder
- decreased function of bone marrow
- low blood counts due to bone marrow failure
- anemia
- decreased blood platelets
- low levels of granulocytes
- a type of white blood cell

Module I Administrative Information

Product Name: Chlomaicol (Chloramphenicol Capsules 250mg)

- a painful condition that affects the nerves in the legs and arms called peripheral neuropathy
- sudden blindness and pain upon moving the eye
- bleeding
- liver problems
- decreased kidney function
- a mother who is producing milk and breastfeeding
- anemia due to depressed bone marrow
- anemia from pyruvate kinase and G6PD deficiencies
- a condition where red blood cells break apart called paroxysmal nocturnal hemoglobinuria

2. Allergies:

- Chloramphenicol
- Amphenicols

Full Drug Information

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2. *Before Using*

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

1. Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Module I Administrative Information

Product Name: Chlomaacol (Chloramphenicol Capsules 250mg)

2. Pediatric

Newborn infants are especially sensitive to the side effects of chloramphenicol because they cannot remove the medicine from their body as well as older children and adults.

3. Geriatric

Many medicines have not been studied specifically in older people. Therefore, it may not be known whether they work exactly the same way they do in younger adults or if they cause different side effects or problems in older people. There is no specific information comparing use of chloramphenicol in the elderly with use in other age groups.

4. Breastfeeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

5. Drug Interactions

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Cholera Vaccine, Live
- Citalopram
- Tacrolimus
- Voriconazole

Using this medicine with any of the following medicines may cause an increased risk of certain side effects, but using both drugs may be the best treatment for you. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Ceftazidime
- Chlorpropamide
- Cyanocobalamin
- Cyclosporine
- Dicumarol
- Fosphenytoin
- Phenytoin
- Rifampin

Module I Administrative Information

Product Name: Chlomaacol (Chloramphenicol Capsules 250mg)

- Rifapentine
- Tetanus Toxoid
- Tolbutamide

6. Other Interactions

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

7. Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Anemia, bleeding, or other blood problems—Chloramphenicol may cause blood problems
- Liver disease—Patients with liver disease may have an increased risk of side effects

3. Proper Use

Chloramphenicol is best taken with a full glass (8 ounces) of water on an empty stomach (either 1 hour before or 2 hours after meals), unless otherwise directed by your doctor.

For patients taking the oral liquid form of this medicine:

- Use a specially marked measuring spoon or other device to measure each dose accurately. The average household teaspoon may not hold the right amount of liquid.

To help clear up your infection completely, keep taking this medicine for the full time of treatment, even if you begin to feel better after a few days. Do not miss any doses.

1. Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For infections caused by bacteria:
 - For oral dosage forms (capsules and suspension):

Module I Administrative Information

Product Name: Chlomaacol (Chloramphenicol Capsules 250mg)

- Adults and teenagers—Dose is based on body weight. The usual dose is 12.5 milligrams (mg) per kilogram (kg) (5.7 mg per pound) of body weight every six hours.
- Children—
 - Infants up to 2 weeks of age: Dose is based on body weight. The usual dose is 6.25 mg per kg (2.8 mg per pound) of body weight every six hours.
 - Infants 2 weeks of age and older: Dose is based on body weight. The usual dose is 12.5 mg per kg (5.7 mg per pound) of body weight every six hours; or 25 mg per kg (11.4 mg per pound) of body weight every twelve hours.
- For injection dosage form:
 - Adults and teenagers—Dose is based on body weight. The usual dose is 12.5 mg per kg (5.7 mg per pound) of body weight every six hours.
 - Children—
 - Infants up to 2 weeks of age: Dose is based on body weight. The usual dose is 6.25 mg per kg (2.8 mg per pound) of body weight every six hours.
 - Infants 2 weeks of age and older: Dose is based on body weight. The usual dose is 12.5 mg per kg (5.7 mg per pound) of body weight every six hours; or 25 mg per kg (11.4 mg per pound) of body weight every twelve hours.

2. Missed Dose

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

3. Storage

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

1. Precautions

If your symptoms do not improve within a few days, or if they become worse, check with your doctor.

It is very important that your doctor check you at regular visits for any blood problems that may be caused by this medicine.

Chloramphenicol may cause blood problems. These problems may result in a greater chance of infection, slow healing, and bleeding of the gums. Therefore, you should be careful when using regular toothbrushes, dental floss, and toothpicks. Dental work, whenever possible, should be done before you begin taking this medicine or delayed until your blood counts have returned to normal. Check with your medical doctor or

Module I Administrative Information

Product Name: Chlomaacol (Chloramphenicol Capsules 250mg)

dentist if you have any questions about proper oral hygiene (mouth care) during treatment.

For diabetic patients:

- This medicine may cause false test results with urine sugar tests. Check with your doctor before changing your diet or the dosage of your diabetes medicine.

2. Side Effects

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Stop taking this medicine and get emergency help immediately if any of the following effects occur:

1. Rare

- Bloating stomach
- drowsiness
- gray skin color
- low body temperature
- uneven breathing
- unresponsiveness

2. Less common

- Pale skin
- sore throat and fever
- unusual bleeding or bruising
- unusual tiredness or weakness (the above side effects may also occur up to weeks or months after you stop taking this medicine)

3. Rare

- Confusion, delirium, or headache
- eye pain, blurred vision, or loss of vision
- numbness, tingling, burning pain, or weakness in the hands or feet
- skin rash, fever, or difficulty in breathing

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of

Module I Administrative Information

Product Name: Chlomaacol (Chloramphenicol Capsules 250mg)

the following side effects continue or are bothersome or if you have any questions about them:

4. Less common

- Diarrhea
- nausea or vomiting

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

Module I Administrative Information

Product Name: Chlomaacol (Chloramphenicol Capsules 250mg)

8. Marketing Authorization Number: ---

9. Date of first Authorization /renewal of the authorization: ---

10. Date of revision of text: October 2016