

i PACKAGE LEAFLET:
Information for the user

KLORAMFENIKOL

Eye drops solution - 0.5%

Ear drops solution – 5%

(Chloramphenicol)

Oral suspension – 125 mg / 5 ml

(Chloramphenicol palmitate)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Kloramfenikol is and what it is used for
2. Before you take Kloramfenikol
3. How to take Kloramfenikol
4. Possible side effects
5. How to store Kloramfenikol
6. Further information

1. WHAT KLORAMFENIKOL IS AND WHAT IT IS USED FOR

Chloramphenicol is a bacteriostatic antibiotic with a broad spectrum of action against both gram-positive and gram-negative bacteria. It has a bactericidal action against the cause of bacterial typho.

Eye drops: Superficial bacterial infections of the eye that affect cornea, conjunctiva, and eyelids, caused by microorganisms sensitive to chloramphenicol.

Ear drops: It is used for the treatment of superficial infections of ear canal (external otitis) caused by gram positive and gram negative sensitive microorganisms.

Oral suspension: Kloramfenikol should be used only in serious infections, in which other less toxic antimicrobials are not effective or are contraindicated. Usually it is used in infections caused from Haemophilus influenzae (ampicillin-resistant) which are life threatening and in typhoid fever.

2. BEFORE YOU TAKE KLORAMFENIKOL

Do not take Kloramfenikol if:

- you are hypersensitive (allergic) to chloramphenicol or to any of the other ingredients of Kloramfenikol products;
- you have renal and liver impairment or during dental procedures;
- you are pregnant or planning to become pregnant;
- you are breast-feeding;
- you have bone-marrow depression or blood dyscrasia;
- you are using drugs that cause depression of the bone – marrow function;
- you have a perforated tympanic membrane (risk for ototoxicity);
- you want to use it in children under 2 years old, because of the "gray baby" syndrome;
- you suffer from porphyria.

It is not advised the use of chloramphenicol in minor infections and as prophylaxis for bacterial infections

Take special care with Kloramfenikol

The prolonged and repeated treatment should be avoided. During treatment for a considerable long time, it is advisable to perform periodic blood tests.

Ask your doctor before you take chloramphenicol:

- if in the past you have had bone-marrow depression or blood dyscrasia;
- if you have impaired renal function or severe renal insufficiency (it should be used in lower doses);
- if you are pregnant. It is advisable not to use chloramphenicol during pregnancy, especially during the third trimester, and also during breast-feeding (chloramphenicol is excreted in breast milk);
- if it is going to be used in children.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Kloramfenikol.

Please tell your doctor or pharmacist if you are taking / using, or have recently taken / used other medicines, including medicines obtained without a prescription.

Do not forget to inform your doctor for the treatment with Kloramfenikol if you receive any other medicine during treatment.

When used locally in the eye or in the ear, it does not appear to interact with other drugs.

It is especially important that in case of oral use, your doctor should be informed that you are being treated with:

- penicillin (concomitant treatment with chloramphenicol influences its action)
- cephalosporin (concomitant treatment with chloramphenicol influences its action)
- aminoglycosides (concomitant treatment with chloramphenicol influences their action)
- erythromycin (displaces it from its site of action in the ribosome)
- vitamin B12 (chloramphenicol antagonises its action)
- folic acid (chloramphenicol antagonises its action)
- ferric salts (chloramphenicol antagonises their action)
- coumarin anticoagulants, clopidogrel;
- phenytoin; fosphenytoin, primidone;
- rifampicin;
- tacrolimus, phenobarbital, clozapine, cyclosporin, sulfonyleuric hypoglycemics.
- hydantoin, because chloramphenicol may increase its serum levels;
- oral contraceptives, because chloramphenicol may decrease their effect.

Taking Kloramfenikol with food and drinks

It is not advisable to take it on empty stomach. It is preferred to take it after food.

Pregnancy

Ask for the advice of your doctor or pharmacist before you take this drug.

There is a risk of damaging the unborn child.

Chloramphenicol should not be used during pregnancy, especially during the third trimester. Therefore, always consult with your doctor before you take chloramphenicol during pregnancy.

Breast-feeding

Chloramphenicol passes into breast milk and therefore should not be used during breast-feeding.

Driving and using machines

This drug taken **orally** does not affect the ability to drive, but if it is used as **eye drops**, it may cause blurring of the vision and it may affect your ability to drive, use machinery or do works which need high concentration.

Important information about some of the ingredients of Kloramfenikol

Kloramfenikol - Eye drops solution contains methyl hydroxybenzoate which may cause allergic reactions (possibly delayed).

Kloramfenikol – Ear drops solution contains propylene glycol which may cause skin irritation.

Kloramfenikol - Oral suspension contains:

- sucrose; if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product;
- methyl hydroxybenzoate and propyl hydroxybenzoate which may cause allergic reactions (possibly delayed).

3. HOW TO TAKE KLORAMFENIKOL

Always take Kloramfenikol exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

If you feel that the effects of Kloramfenikol are too strong or too weak, talk to your doctor or pharmacist.

Dosage

Eye drops: it is used 1 drop every 2 hours. The frequency of administration is reduced when the control of the infection is achieved. The treatment continues for another 48 hours after the healing of the infection. It should not be used for longer than 5 days.

Ear drops: 2-3 drops 3 times a day in the affected ear.

Oral suspension:

- In adults the usual dose is 50 mg / kg per day, divided in 4 doses.
- In severe forms of infections (sepsis or meningitis) the doses may be

doubled, on condition to reduce it immediately after the clinical improvement is certified.

Your doctor will advise you according the circumstances.

Chloramphenicol products are not recommended to be used in children under 2 years old because of the "gray baby" syndrome. Even in older pediatric ages, the use should be justified by the doctor.

If you take more Kloramfenikol than you should

If you take more Kloramfenikol (orally) than the amount that should be taken, or if the children have taken it by mistake, please contact your doctor, hospital or call the emergency to get an opinion on the risk and advice on the actions to be taken.

In the case of **eye drops** or **ear drops** an overdose is less possible.

If you forget to take Kloramfenikol

If you forget a dose (or more than one dose), take your next dose when it is time to take it usually.

Do not take a double dose (or more) to make up the missed dose (doses).

If you have further questions about the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Kloramfenikol may cause side effects, although not everybody manifests them.

- Hypersensitivity reactions can be observed.
- Chloramphenicol may cause reversible toxicological effects in the bone-marrow, that appear with: anaemia, reticulopenia, leukemia, or thrombocytopenia.

Their intensity depends only on the used dose. These effects are usual when the blood concentration of chloramphenicol is higher than 25 µg/ml.

- Chloramphenicol may also cause an irreversible depression of the bone-marrow, which appears with aplastic anaemia. This kind of toxicity (idiosyncrasia) does not depend on the dose and may appear even after a single dose, as well as several months after discontinuation of the treatment.
- "Gray syndrome" (characterised by abdominal disturbances, vomiting, gray colour, hypothermia, irregular respiration, progressive pallid cyanosis, circulatory collapse and possible death in a few hours).
- Other side effects are: optic neuritis, peripheral neuritis, neurotoxicity usually of a mild form (headache, depression, confusion, delirium).

Rare side effects include: nausea, vomiting, diarrhea, taste disturbances, glossitis, stomatitis, anal pruritus, enterocolitis, nocturnal hemoglobinuria.

- Compared to other antibiotics used in ophthalmology, Kloramfenikol is among those with the lowest ocular toxicity.
- The local use may be accompanied with maculopapular rash, urticaria, pruritus and vesicular dermatitis.

5. HOW TO STORE KLORAMFENIKOL

Keep out of the reach and sight of children!

Do not use Kloramfenikol after the expiry date stated on the package.

Do not store above 25 °C.

Keep in the original packaging to protect it from light and humidity.

6. FURTHER INFORMATION

What Kloramfenikol - Eye drops solution contains

The active substance is chloramphenicol.

1 ml solution contains 5 mg chloramphenicol (0.5%).

The other ingredients: boric acid, borax, methyl hydroxybenzoate, water for injection.

What Kloramfenikol - Ear drops solution contains

The active substance is chloramphenicol.

1 ml solution contains 50 mg chloramphenicol (5%).

The other ingredients: propylene glycol.

What Kloramfenikol – Oral suspension contains

The active substance is chloramphenicol palmitate.

5 ml suspension contain chloramphenicol palmitate equivalent to 125 mg chloramphenicol.

The other ingredients: polysorbate 80, glycerin, sodium carboxymethyl-cellulose, sodium benzoate, sucrose, citric acid, ethyl alcohol, methyl hydroxybenzoate, propyl hydroxybenzoate, vanilla, essence caramel, purified water.

Content of the pack

Eye drops: Box with a 10 ml flacon

Ear drops: Box with a 10 ml flacon

Oral suspension: Box with a 60 ml glass flacon.

Explanatory of the illustration icons on the packaging:

 Ask your doctor or pharmacist.

 Content.  Warning.

 Eye drops.

 Ear drops.

 Oral suspension.

Marketing Authorisation Holder (MAH) and Manufacturer:

 **PROFARMA Sh.a.**
Rruga "Myslym Keta"
Tel.: 00355 4 23 89 602
Tirana - ALBANIA

This leaflet was last revised in April 2016.