

i **PACKAGE LEAFLET:**
Information for the user

KLORAMFENIKOL

Tablets - 250 mg
(Chloramphenicol)

Read 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 signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects 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. Other information

1. WHAT KLORAMFENIKOL IS AND WHAT IT IS USED FOR

Chloramphenicol is a bacteriostatic antibiotic with a broad spectrum of action. Chloramphenicol is rapidly absorbed by the intestinal tract, while its bioavailability is 75 % up to 90 %. The maximal plasmatic concentration is 10 up to 200 mcg/ml. About 60 % of the chloramphenicol is bound with plasmatic proteins. Chloramphenicol enters in the cerebrospinal fluid, even in the absence of inflamed meninges. The general urinary excretion of chloramphenicol fluctuates from 68 % up to 99 % for three days. The major part of chloramphenicol present in blood is in the active form. The elimination half - life of chloramphenicol is about 4 hours.

Kloramfenikol tablet is used in life - threatening infections, mainly those caused by *Haemophilus influenzae*, and in the typhoid fever. Kloramfenikol should not be used if other safer alternative drugs exist.

2. BEFORE YOU TAKE KLORAMFENIKOL
Do not take Kloramfenikol if:

- you are sensitive (allergic) to chloramphenicol or to any of the other excipients of Kloramfenikol tablets;
- you have mild infections;
- you have severe renal impairment;
- you have severe renal failure;
- you have liver impairment;
- you are in the period of pregnancy and breast - feeding;
- you have bone marrow depression and blood dyscrasia;
- you are using drugs liable to depress bone marrow function;
- you have porphyria.

Kloramfenikol is contraindicated in newborns because it causes the "grey syndrome".

Take special care with Kloramfenikol

Ask your doctor before taking Kloramfenikol. Kloramfenikol should be used with caution in patients with renal impairment. Kloramfenikol may reduce the hematologic effects of vitamin B12 and iron preparations in patients with pernicious anemia or with iron deficiency; for this reason they should not be used simultaneously. During the use of Kloramfenikol, it is advised to do periodic controls of the blood formula.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Kloramfenikol. Please contact your doctor or pharmacist if you are taking or have recently taken other drugs, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Kloramfenikol if you have been given any other drug during treatment.

Kloramfenikol is deactivated in the liver and thus it may interact with drugs that are metabolised by mycosomal enzymes of the liver.

It is especially important that your doctor be aware of the fact that you are being treated with:

- hidantoinis, because Kloramfenikol may increase their levels in serum;
- oral contraceptives, because chloramphenicol may reduce their effect;
- vitamin B12 and iron preparations, because chloramphenicol may reduce their effect;
- oral anticoagulants, because chloramphenicol may increase their effect;
- rifampicin, because it may reduce the plasma levels of chloramphenicol;
- antidiabetics, because chloramphenicol potentiates the effects of sulfonilureas;
- clozapine;
- ciclosporin;
- clopidogrel;
- tacrolimus;
- barbiturates, because they reduce the efficacy of chloramphenicol.

Pregnancy

Ask for the advice of the pharmacist or of the doctor before taking this drug.

Kloramfenikol is not recommended during pregnancy, especially during the last trimester, because of the risk of "grey syndrome" in newborns.

Breast - feeding

Kloramfenikol passes into breastmilk and therefore it should not be used during breast - feeding.

Driving and using machinery

Kloramfenikol can cause central nervous system disorders (headache, confusion, delirium, mild depression, and visual disorders), which may impair the ability to drive and use machinery.

3. HOW TO TAKE KLORAMFENIKOL

Always take Kloramfenikol as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If you feel that the effects of Kloramfenikol are too strong or too weak, talk to your doctor or pharmacist. The tablets should be swallowed with at least half glass of water. The usual dose is 1 - 2 g, which is given in 4 equal doses (every 6 hours), dependently on the infection importance. The treatment should continue for at least 24 - 48 hours after the symptoms disappear. Kloramfenikol should be used 1 hour before or 2 hours after meals, with plenty of liquid. Kloramfenikol should not be taken for a long time or repeatedly.

The use in children should be justified by the doctor. Your doctor will advise you accordingly to the circumstances.

If you take more Kloramfenikol

If you take more Kloramfenikol than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

If you forget to take Kloramfenikol

If you forget a dose (or more doses), take the next dose when it is time to take it usually. Do not take a double dose (or higher) to make up for a forgotten dose (doses). If you have further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Kloramfenikol may cause side effects, although not everybody manifests them. Sometimes they are serious, sometimes not. Do not get alarmed by this list of possible side effects. None of them may appear to you.

The most common side effects are:

- hematologic effects (bone marrow depression, aplastic anemia, nocturnal hemoglobinuria, hypoplastic anemia, thrombocytopenia);
- central nervous system effects (headache, mental confusion, delirium, mild depression, optic neuritis, peripheral neuritis);
- in the digestive tract (diarrhea, nausea, vomiting, glossitis, stomatitis);
- "grey syndrome" (appears with abdominal disorders, vomiting, grey colour, hypothermia, irregular breathing, pallid progressive cyanosis and circulatory collapse and after a few hours the patient may die).

Hypersensitivity reactions are also noticed (e.g. fever, exanthema, angioedema, urticaria, anaphylaxis).

If any of the side effects worsens, or if you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE KLORAMFENIKOL

Keep out of the reach and sight of children! Do not use Kloramfenikol after the expiry date which is stated on the package.

Store below 25°C.
Store in the original packaging to protect it from light and humidity.

6. OTHER INFORMATION

What Kloramfenikol 250 mg - tablet contains
The active substance is chloramphenicol. Each tablet contains 250 mg chloramphenicol. The other excipients are: starch, microcrystalline cellulose, gelatin, sodium starch glycolate, magnesium stearate.

Content of the pack

Carton box with 30 tablets.

Explanatory of the illustration icons on the packaging:

- ! According to medical prescription.
- X Should not be used during pregnancy.
- Content.
- ! Warning.
- Tablet shape.

Marketing Authorisation Holder (MAH) and Manufacturer:

 **PROFARMA Sh.a**
Rruga "Myslym Keta"
Tel.: 00 355 4 23 89 602
Tirana - ALBANIA

This leaflet was last revised in July 2015.

PAY ATTENTION, all the layers are visible.

If you have to print this document please check or uncheck the specific layers.