PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

CHLORAMPHENICOL is an oral Capsule

Composition:

Each Capsule contains:

CHLORAMPHENICOL BP......250mg

Read all of this leaflet carefully before you start using 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 you get side effects and they become serious or if you notice any side

effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet

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

1. WHAT CHLORAMPHENICOL CAPSULE IS AND WHAT IT IS USED FOR?

Chloramphenicol capsules contain chloramphenicol which is an antibiotic for specific uses.

They are used for the treatment of typhoid fever and other dangerous infections where other antibiotics are not effective.

2. BEFORE YOU TAKE CHLORAMPHENICOL

CAPSULEContraindication

Do not take Chloramphenicol if you are allergic to chloramphenicol or any of the other ingredients. if you have recently been vaccinated, pregnant or are breast-feeding, if you have porphyria, a minor infection, are taking medicines that may suppress your bone marrow.

Special warnings and precautions for use

Take special care with Chloramphenicol capsules

Before taking the capsules, tell your doctor if you have liver or kidney problems, are elderly and Taking other medicines

Interaction with other medicinal products and food:

Chloramphenicol is a potent inhibitor of the cytochrome P450 isoforms CYP2C19 and CYP3A4 in the liver. Inhibition of CYP2C19 causes decreased metabolism and therefore increased levels of, for example, antidepressants, antiepileptics, proton-pump inhibitors, and anticoagulants if they are given concomitantly. Inhibition of CYP3A4 causes increased levels of, for example, calcium channel blockers, immunosuppressants, chemotherapeutic drugs, benzodiazepines, azole antifungals, tricyclic antidepressants, macrolide antibiotics, SSRIs, statins, cardiac antiarrhythmics, antivirals, anticoagulants, and PDE5 inhibitors.

Pregnancy and Lactation:

DO NOT take Chloramphenicol capsules if you are pregnant, planning to become pregnant or breast-feeding as they may harm the baby. Chloramphenicol may cause a condition called Grey Baby Syndrome, where the baby's skin appears grey and the baby is listless and weak. This may be fatal and requires immediate medical attention. Ask your doctor for advice before taking any medicine.

Driving and using machines

Chloramphenicol capsules are unlikely to affect your ability to operate machinery or to drive.

3. HOW TO TAKE CHLORAMPHENICOL CAPSULE

Always take CHLORAMPHENICOL Capsule exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is:

Adults and children over 12 years: 500 mg (2 capsules) every 6 hours

If you take more CHLORAMPHENICOL Capsule than you should

If you take more CHLORAMPHENICOL Capsule than you should, talk to a doctor or go to the nearest hospital.

If you forget to take CHLORAMPHENICOL Capsule

- Do not take the missed dose
- Take your next dose at the usual time, and then keep taking your medicine

as your doctor has told you

• Do not take a double dose to make up for a forgotten dose If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you stop taking CHLORAMPHENICOL Capsule

You should continue taking Chloramphenicol for as long as your doctor has told you to, even if you start to feel better. If you stop before finishing the prescribed course of treatment your infection may still be present or may reappear.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, CHLORAMPHENICOL Capsule can cause side effects, although not everybody gets them.

CHLORAMPHENICOL Side effects include; Anemia, Dark colored urine, Sore throat and fever, Unusual bleeding or bruising, Difficulty in breathing, Headache, Nausea and Vomiting, Burning, numbness, tingling in the arms and feet, Swelling of face, lips, eyelids, tongue, hands and feet, Depression.

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.

5. HOW TO STORE CHLORAMPHENICOL CAPSULE

Keep out of the sight and reach of children

Store below 30°C, protect from light.

Store in the original Carton.

Do not take CHLORAMPHENICOL Capsule after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your Pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

The active substance in CHLORAMPHENICOL Capsule is:

Each Capsule contain:

Chloramphenicol BP......250mg

The other ingredients are:

Starch

Magnesium Stearate

What CHLORAMPHENICOL Capsule looks like and contents of the pack:

CHLORAMPHENICOL is an IVORY/IVORY colour size "1" hard gelatin capsules containing almost white colour free flowing powder. Alu-PVC blister of 10 Capsules, such 50 blisters are packed in carton along with the pack insert.

MANUFACTURER MANUFACTURED BY: NEW GLOBAL PHARMACEUTICALS LTD. P. O. BOX 2448

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