



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

CHLOROQUINE PHOSPHATE INJECTION

Chloroquine phosphate injection 322mg/5ml

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

- You may need to read it again before, during or after use of this medicine.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. 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 become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

1. What Chloroquine Phosphate Injection is and what it is used for
2. What you need to know before you take Chloroquine Phosphate Injection
3. How to take Chloroquine Phosphate Injection
4. Possible side effects
5. How to store Chloroquine Phosphate Injection
6. Contents of the pack and other information

1. WHAT CHLOROQUINE PHOSPHATE INJECTION IS AND WHAT IT IS USED FOR

Chloroquine phosphate Injection is a sterile 4- aminoquinoline compound for parenteral administration. It is an antimalarial and amoebicidal drug. Chloroquine Phosphate Injection is used in the treatment of extraintestinal amebiasis and for treatment of acute attacks of malaria due to *P. vivax*, *P. malariae*, *P. ovale*, and susceptible strains of *P. falciparum* when oral therapy is not feasible.

2. WHAT YOU NEED TO KNOW BEFORE TAKING CHLOROQUINE PHOSPHATE INJECTION

Do not take chloroquine phosphate injection if:

- You are allergic to Chloroquine or any of the other ingredients of the injection.
- You are taking a medicine called amiodarone (used to control the heart rate). Chloroquine Phosphate may increase the risk of uneven heart beats (cardiac arrhythmias) when it is taken at the same time as amiodarone. Check with your doctor or pharmacist if you are not sure.

Take special care with Chloroquine Phosphate Injection if:

- You have ever had epilepsy, convulsions or fits.
- You have ever had problems with your liver or kidneys.
- You have been told that you have a rare disease of the blood pigment called 'Porphyria' or anyone in your family has it.
- You have a scaly condition of the skin called Psoriasis.
- You have a muscle problem called 'myasthenia gravis'. Chloroquine can increase the symptoms of this condition. It can reduce the effect of medicines used to treat this condition (Neostigmine and Pyridostigmine).



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

CHLOROQUINE PHOSPHATE INJECTION

Chloroquine phosphate injection 322mg/5ml

- You have a blood problem called 'glucose-6-phosphate dehydrogenase deficiency'. Chloroquine may damage blood cells in people with this condition. If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Chloroquine injection. Chloroquine can cause lowering of the blood glucose level. Please ask your doctor to inform you of signs and symptoms of low blood glucose levels. A check of the blood glucose level may be necessary.

Chloroquine may cause heart rhythm disorders in some patients: caution should be taken when using Chloroquine, if you were born with or have a family history of prolonged QT interval, if you have acquired QT prolongation (seen on ECG, electrical recording of the heart), if you have heart disorders or have a history of heart attack (myocardial infarction), if you have salt imbalance in the blood (especially low level of Potassium or Magnesium. If you experience palpitations or irregular heartbeat during the period of treatment, you should inform your doctor immediately. The risk of heart problems may increase with increase of the dose. Therefore, the recommended dosage should be followed. If you live in a country where malaria occurs, you may already be slightly immune to the disease. You must ask a doctor or pharmacist for advice before you take anti-malarial medicines.

Taking other medicines with chloroquine phosphate injection

Please tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. Amiodarone (used to control heart rate) must not be taken at the same time as chloroquine (see section Tell your doctor or pharmacist if you are taking any of the following medicines. This is because chloroquine may affect the amount of these medicines in your blood.

- Praziquantel (used to treat infections of the bowel and bladder caused by parasites).
- Cyclosporine (mainly used by transplant patients but also used to treat rheumatoid arthritis and psoriasis).
- Anti-convulsant medicines (used to prevent convulsions and fits).
- Digoxin (used to treat heart problems).

Also tell your doctor or pharmacist if you are taking any of the following medicines:

- Warfarin or other medicines used to prevent blood clots.
- Medicines known to affect the rhythm of your heart. This includes medicines used for abnormal heart rhythm (antiarrhythmics), for depression (tricyclic antidepressants) for psychiatric disorders (antipsychotics), for bacterial infections or against malaria (e.g., Halofantrine)
- Mefloquine, taken to prevent malaria may increase the risk of convulsions or fits when taken at the same time as Chloroquine.
- Levothyroxine (thyroid medicine)
- Medicines used to treat epilepsy, as Chloroquine may reduce their effectiveness.



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

CHLOROQUINE PHOSPHATE INJECTION

Chloroquine phosphate injection 322mg/5ml

- Agalsidase (used to treat Fabry disease), as chloroquine may reduce its activity.
- Cimetidine (used to treat stomach problems). This medicine affects how chloroquine is broken down by your body and may affect the amount of Chloroquine in your blood.
- Medicines like Kaolin (used for diarrhoea) which are called adsorbents.
- Antacids (Aluminum, Calcium and Magnesium salts that are used to treat heartburn or indigestion). Antacids may reduce the amount of Chloroquine absorbed from your gut. This may mean that the full dose of Chloroquine is not absorbed into your body, and it will not work properly. Therefore, you should take your antacid dose at least four hours before or after taking your Chloroquine dose.
- Some medicines (for example, Ciprofloxacin, Cimetidine, Omeprazole, Pyrimethamine) may increase the amount of Chloroquine in your body and this can cause side effects. It is important that you do not take any additional medicines (either prescribed or non-prescribed) before speaking to your doctor.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or may become pregnant, talk to a doctor or pharmacist:

- Before taking Chloroquine Phosphate Injection
- Before you take any medicines to prevent malaria and before you go to a country where there is malaria

Breast-feeding

If you are breast feeding, talk to a doctor or pharmacist before taking Chloroquine Phosphate Injection. Although Chloroquine is passed into breast milk, the amount is not enough to protect your baby from malaria. Therefore, your baby will still need to be given anti-malarial medicines. Ask your doctor or pharmacist who will be able to give you advice.

Driving and using machines

Chloroquine Phosphate Injection is likely to affect your ability to drive or use machines. Sometimes chloroquine phosphate injection causes blurred eyesight or make it difficult to focus your eyes. If this happens to you, do not drive, or use any tools or machines.



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

CHLOROQUINE PHOSPHATE INJECTION

Chloroquine phosphate injection 322mg/5ml

3. HOW TO TAKE CHLOROQUINE PHOSPHATE

In uncomplicated malaria, the standard treatment regimen for Chloroquine against sensitive parasites is a total dose of 25 mg base/kg, usually given as an initial dose of 10 mg/kg followed by 5 mg/kg at 12-hourly intervals.

When given parentally, an initial dose of 10 mg base/kg should be given over a period of 8 hours by slow intravenous infusion.

Subsequent infusions of 5 mg base /kg should be given every 8 hours up to a total dose of 25 mg base/kg.

Chloroquine can be administered by intramuscular or subcutaneous injection at a dose of 3.5 mg base/kg 6-hourly up to a total dose of 25 mg base/kg.

Always take chloroquine phosphate as your healthcare provider instructs you to

If this medicine is from your doctor or pharmacist, take it exactly as they have told you. Otherwise, follow the instructions below. If you do not understand the instructions, or you are not sure, ask your doctor or pharmacist.

When to start taking your medicine

Start taking this medicine one week before you enter the malaria area.

You must continue to take it during your stay. You must keep taking this medicine for 4 weeks after leaving the malaria area.

If you take more chloroquine phosphate injection than you should

If you take too much Chloroquine Phosphate Injection, inform your health care provider, or contact the nearest hospital for further advice.

If you forget to take Chloroquine Phosphate Injection

If you forget to take a dose of Chloroquine, take it as soon as you remember.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Chloroquine Phosphate Injection can cause side effects, but not everybody gets them.

If you have an allergic reaction, stop using chloroquine phosphate injection and get medical help or contact your doctor straight away. The signs may include:

- Difficulty in breathing
- Swelling of the face, lips, tongue or throat which may cause difficulty in swallowing.
- An itchy rash (similar to nettles or hives).
- Other possible side effects



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

CHLOROQUINE PHOSPHATE INJECTION

Chloroquine phosphate injection 322mg/5ml

Heart

- Changes in the way your heart works (known as 'electrocardiographic changes').
- Low blood pressure. This may make you feel faint or dizzy.
- Cardiac muscle disease (cardiomyopathy) which may be fatal in case of high-dose long-term use (rare).
- Abnormal heart rhythm, life-threatening irregular heart rhythm (seen on ECG).

Lungs

- Inflammation of the lungs causing a condition known as diffuse parenchymal lung disease. If you develop serious breathlessness or worsening of breathlessness, seek prompt medical advice.

Mouth

- Mouth ulcers.
- Inflamed mouth.

Nervous system

- Headache.
- Feeling dizzy or lightheaded.
- Convulsions or fits.
- Involuntary muscle movements or spasms.
- Insomnia
- Mood changes or other effects on behaviour. These include feeling: depressed, confused, anxious or rarely, seeing, feeling, or hearing things that are not there (hallucinations).

Skin

- Skin rash, including a scaly rash (psoriasis) or itch, which sometimes causes swelling of the affected area.
- Peeling or scaly skin

5. HOW TO STORE CHLOROQUINE PHOSPHATE INJECTION

- Keep all medicines out of reach of children.
- Store below 30°C
- Do not administer after the expiry date 'EXP' stated on the carton. 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 that are no longer required. This will help to protect the environment.



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

CHLOROQUINE PHOSPHATE INJECTION

Chloroquine phosphate injection 322mg/5ml

6. FURTHER INFORMATION

What Chloroquine phosphate injection contains


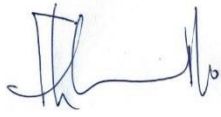

The active substance of Chloroquine Phosphate Injection is Chloroquine Phosphate 322mg/5ml.

What Chloroquine phosphate injection looks like.

10 x 5ml ampoule placed in a carton.

MANUFACTURER

Fidson Healthcare Plc,
17-21, Fidson Avenue
Sango-Ota, Ogun State,
Nigeria.

	Prepared by	Approved by	
Signature			
Date	09/02/2024	05-02-2024	23-05-2024
Designation	AMRA	HoM	HQRA