

1. Name of the proprietary product: FEST CHLOROQUINE 40 MG INJECTION

Name of the nonproprietary International Product: Chloroquine Phosphate Injection

Route of Administration: Intramuscular, Intravenous injections

2. Qualitative and Quantitative composition:

Sr. No	Ingredients	Specification	Label Claim	Qty/ ml(mg)	Qty/ vial (gm)	Reason for inclusion
ACTIVE						
1.	Chloroquine Phosphate Eq to Chloroquine	BP	40 mg	64.50 40.0	1.935	Active
EXCIPIENTS						
2.	Benzyl Alcohol	BP	2% v/v	0.02 ml	0.6 ml	Preservative
3.	Water for Injection	BP	--	q.s.	q.s.	Solvent

Where, BP- British Pharmacopoeia, q.s.- quantity sufficient

Calculation:

Molecular weight of Chloroquine Phosphate 515.865

Molecular weight of Chloroquine 319.872

519.9 of Chloroquine Phosphate is equivalent to 319.9 Chloroquine

Therefore, 64.50 chloroquine phosphate is equivalent to 40 mg chloroquine.

3. Pharmaceutical Form: Injection

Clear colourless liquid filled in 30 ml amber colour glass vial sealed with flip off. Such 10 vials packed in carton along with pack insert.

4. Clinical Particulars:

4.1 Therapeutic Indications:

Chloroquine is used for the treatment of Rheumatoid Arthritis and Lupus Erythematosus

4.2 Posology and method of administration:

Adult: 200 to 300 mg chloroquine base by intramuscular or intravenous injection. It should not be given intravenously to children.

4.3 Contraindications

Care is needed in administering chloroquine to patients with impaired liver or renal function or with porphyria.

4.4 Special warnings and precautions for use

Contraindicated in patients hypersensitive to drug and in those with retinal or visual field changes or porphyria. Use cautiously in patients with hepatic disease, alcoholism, or in conjunction with hepatotoxic drugs. Use cautiously in patients with blood disorders or G6-PD deficiency.

4.5 Interaction with other medicinal products and other forms of interaction:

If you use other drugs or over the counter products at the same time, the effects of Fest Chloroquine 40 mg Injection may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that your doctor can help you prevent or manage drug interactions. Fest Chloroquine 40 mg Injection may interact with the following drugs and products:

Arsenic trioxide
Cisapride
Dofetilide
Erythromycin
Fluconazole
Levofloxacin
Methadone

4.6 Pregnancy and Lactation:

Breast-feeding patients

- Drug appears in breast milk. Safety hasn't been established. Use cautiously in breast-feeding women.

Pediatric patients

- Children are extremely susceptible to toxicity; monitor children closely for adverse effects.

4.7 Effects on the ability to drive and use machines

One should not drive a vehicle if using the medicine makes you drowsy, dizzy or lowers your blood-pressure extensively.

4.8 Undesirable effects:

Administration must be monitored as cardiovascular collapse with or without cardiac arrhythmia may occur especially after intravenous administration and even after the conventional mode of administration.

Pruritus is a common side-effect; headache and visual and gastrointestinal disturbances occasionally arise, but disappear on discontinuation of treatment. Blood dyscrasias have occasionally been reported.

4.9 Overdose

Headache, drowsiness, respiratory and cardiovascular depression, arrhythmias, shock, visual disturbances, convulsions, respiratory and cardiac arrest. Overdosage is more likely in children and with intravenous administration. Treatment of overdosage is symptomatic and supportive.

5. Pharmacological Particulars:

5.1 Pharmacodynamic properties
Pharmacotherapeutic group:
Antirheumatics

ATC code: P01BA01

Action: Chloroquine binds to DNA, interfering with protein synthesis. It also inhibits DNA and RNA polymerases.

Amebicidal action: Unknown.

Anti-inflammatory action: Unknown. Drug may antagonize histamine and serotonin and inhibit prostaglandin effects by inhibiting conversion of arachidonic acid to prostaglandin F2; it also may inhibit chemotaxis of polymorphonuclear leukocytes, macrophages, and eosinophils.

5.2 Pharmacokinetic properties

Absorption: Absorbed readily and almost completely.

Distribution: 55% bound to plasma proteins. Concentrated in erythrocytes, liver, spleen, kidneys, heart, and brain and is strongly bound in melanin-containing cells.

Metabolism: About 30% of an administered dose is metabolized by the liver to monodesethyl-chloroquine and bidesethylchloroquine.

Excretion: About 70% of dose is excreted unchanged in urine; unabsorbed drug is excreted in feces. Small amounts of the drug may be present in urine for months after the drug is discontinued. Renal excretion is enhanced by urinary acidification.

Route	Onset	Peak	Duration
P.O.	Unknown	1-3 hr	Unknown
I.M.	Unknown	1/2 hr	Unknown

5.3 Pre-clinical Safety:

Administration must be monitored as cardiovascular collapse with or without cardiac arrhythmia may occur especially after intravenous administration and even after the conventional mode of administration.

Pruritus is a common side-effect; headache and visual and gastrointestinal disturbances occasionally arise, but disappear on discontinuation of treatment. Blood dyscrasias have occasionally been reported.

6. Pharmaceutical Particulars:

List of Excipients:

No excipients added.

6.2 Incompatibilities:

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf Life: 36 months

6.4 Special Precautions for storage:

Store below 30°C in a dry place, protected from light.

The reconstituted solution should be stored below 30°C and should be used within 1hour.

6.5 Nature and contents of container:

Clear colourless solution filled in 30 ml amber colour glass vial with flip off Seal cap, Such 10 Vials packed in a primary Carton along with Pack insert.

6.6 Special precautions for disposal and other handling:

No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder:

**FEST PHARMACEUTICAL NIGERIA LTD,
61, Emir Road, Sabon Gari, Kano, Kano State, Nigeria.**

MANUFACTURER:

PHARMAX INDIA PRIVATE LIMITED.
9, Kurla Industrial Estate, Ghatkopar (W),
Mumbai - 400 086, India.s

8. Marketing Authorization Number: ---

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

10. Date of revision of text:



**National Agency for Food & Drug Administration &
Control (NAFDAC)**

Registration & Regulatory Affairs (R & R) Directorate

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

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

- Keep this leaflet. 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 FEST CHLOROQUINE 40 MG INJECTION is and what it is used for
2. What you need to know before you take FEST CHLOROQUINE 40 MG INJECTION.
3. How to take FEST CHLOROQUINE 40 MG INJECTION.
4. Possible side effects
5. How to store FEST CHLOROQUINE 40 MG INJECTION.
6. Contents of the pack and other information

1. WHAT FEST CHLOROQUINE 40 MG INJECTION IS AND WHAT IT IS USED FOR

Fest Chloroquine 40 mg Injection is a sterile 4- aminoquinoline compound for parenteral administration. It is an Chloroquine is used for the treatment of Rheumatoid Arthritis and Lupus Erythematosus drug. Fest Chloroquine 40 mg Injection is used in the treatment of extraintestinal amebiasis and for treatment of acute attacks of extraintestinal amebiasis.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FEST CHLOROQUINE 40 MG INJECTION.

Do not take FEST CHLOROQUINE 40 MG INJECTION if you

- 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). Fest Chloroquine 40 mg Injection 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 Fesr Chloroquine 40 mg 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).
- 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 Fest Chloroquine 40 mg 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 Fest Chloroquine 40 mg 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.
- 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 nonprescribed) 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 Fest Chloroquine 40 mg 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 Fest Chloroquine 40 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

One should not drive a vehicle if using the medicine makes you drowsy, dizzy or lowers your blood-pressure extensively.

3. HOW TO TAKE FEST CHLOROQUINE 40 MG INJECTION

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 Fest Chloroquine 40 mg Injection 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 Fest Chloroquine 40 mg injection than you should

If you take too much Fest Chloroquine 40 mg Injection, inform your health care provider, or contact the nearest hospital for further advice.

If you forget to take Fest Chloroquine 40 mg Injection

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Fest Chloroquine 40 mg Injection can cause side effects, but not everybody gets them.

If you have an allergic reaction, stop using Fest Chloroquine 40 mg 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

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 longterm 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 FEST CHLOROQUINE 40 MG INJECTION

- Keep all medicines out of reach of children.
- Store below 30°C
- The reconstituted solution should be stored below 30°C and should be used within 1 hour.
- 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.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Fest Chloroquine 40 mg injection looks like.

30 ml x 10 vial placed in a carton.

Clear colourless solution filled in 30 ml amber colour glass vial with flip off Seal cap, Such 10 Vials packed in a primary Carton along with Pack insert.

MANUFACTURER

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Maharashtra, India.

APPLICANT /MAH

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