

Package leaflet: Information for the user

Chloroquine phosphate 250 mg Tablets (chloroquine)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Chloroquine phosphate is and what it is used for

Chloroquine phosphate belongs to a group of medicines called ‘anti-malarials’. ‘Anti-malarials’ can be taken in certain parts of the world to help prevent malaria. This is a serious disease spread by infected mosquitoes Chloroquine phosphate will give some degree of protection (prophylaxis) against malaria in certain countries.

Medicines to help prevent malaria (malaria prophylaxis) are recommended for:

- People travelling to countries where malaria occurs.
- People living in malaria areas who are not immune to malaria.

These people have little or no immunity to malaria, so they are at risk of severe attacks.

You must get medical advice on which anti-malarial medicines to take. You must ask your doctor or pharmacist if Chloroquine phosphate is suitable for the part of the world that you are visiting. In some countries you may have to take Chloroquine phosphate with another medicine for maximum protection.

Avoiding mosquito bites

When you are taking this medicine to prevent malaria, you should also reduce the chances of being bitten by mosquitoes.

- Wear light-coloured, long-sleeved clothing and long trousers when you are outside after sunset.
- Use insect repellent creams or sprays on parts of your body not covered by clothing.
- Sleep in a properly screened room or under a mosquito net.
- Spray to kill any mosquitoes that may have entered rooms in spite of screening.

Signs of malaria

No medicine can be guaranteed to protect against malaria in every case. **If you have a high temperature (fever) during your visit to a malaria area, or up to a year after returning home, you should suspect malaria.** Contact a doctor straight away and let him or her know that you have visited a malaria area.

2. What you need to know before you take Chloroquine phosphate

Do not take Chloroquine phosphate if:

- You are allergic to chloroquine phosphate or any of the other ingredients of chloroquine phosphate (see Section 6: Contents of the pack and other information).
- 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Chloroquine phosphate if:

- You have ever had epilepsy, convulsions or fits.
- You have ever had problems with your liver or kidneys.
- You have ever been told that you have a rare disease of the blood pigment called ‘porphyria’ or anyone in your family has it. This is because Chloroquine phosphate may cause severe symptoms of porphyria, particularly if you drink alcohol.
- You have a scaly condition of the skin called psoriasis.
- You have a muscle problem called ‘myasthenia gravis’. Chloroquine phosphate can increase the symptoms of this condition. It can also reduce the effect of medicines used to treat this condition (neostigmine and pyridostigmine).
- You have cardiomyopathy (problems with the muscles in your heart) or prolongation of QTc interval (disturbance of the heart’s electrical system).
- You have a blood problem called ‘glucose-6-phosphate dehydrogenase deficiency’. Chloroquine phosphate may damage blood cells in people with this blood condition.

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 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, see section “Other medicines and Chloroquine”).

If you experience palpitations or irregular heart beat 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 are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Chloroquine.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Chloroquine phosphate.

If you go into hospital, tell the medical staff that you are taking Chloroquine phosphate.

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.

Some people being treated with Chloroquine can experience mental health problems such as irrational thoughts, hallucinations, feeling confused, aggressiveness, paranoia, feeling depressed or have thoughts of self-harm or suicide, even those who have never had similar problems before. If you or others around you notice any of these side effects (see section 4) seek medical advice straight away.

Other medicines and Chloroquine phosphate

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 phosphate (see section 2: what you need to know before you take Chloroquine phosphate).

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).
- Ciclosporin (mainly used by transplant patients but also used to treat rheumatoid arthritis and psoriasis).
- Anti-convulsant medicines (used to prevent convulsions or fits).
- Digoxin (used to treat heart problems). Azithromycin (e.g. a group of medicines called macrolides), clarithromycin, or erythromycin (antibiotics used for treating infections). Taking these medicines at the same time as chloroquine may increase the chance of you getting side effects that affect your heart.

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

- Halofantrine (to treat malaria) or moxifloxacin (antibiotic). There is a risk of irregular heartbeats when taken with Chloroquine phosphate.
- Other medicines used to prevent malaria, such as mefloquine. There is a risk of convulsions or fits when these medicines are taken at the same time as Chloroquine phosphate.
- 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).
- Medicines used to treat epilepsy, as Chloroquine phosphate may reduce their effectiveness.
- Agalsidase (used to treat Fabry Disease), as Chloroquine phosphate may reduce its activity.
- Cimetidine (used to treat stomach problems). This medicine affects how Chloroquine phosphate is broken down by your body and may affect the amount of Chloroquine phosphate in your blood.
- Medicines like kaolin (used for diarrhoea) which are called ‘adsorbents’.
- Levothyroxine (thyroid medicine).

Antacid medicines (aluminium, calcium and magnesium salts that are used to treat heartburn or indigestion). Adsorbents and antacid medicines may reduce the amount of Chloroquine phosphate absorbed from your gut. This may mean that the full dose of Chloroquine phosphate is not absorbed into your body and it will not work properly. Therefore, you should take these medicines at least four hours before or after taking your Chloroquine phosphate dose.

Some medicines (for example, ciprofloxacin, cimetidine, omeprazole, pyrimethamine) may increase the amount of Chloroquine phosphate 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.

If you need a vaccination against rabies, make sure you have it before you start your anti-malarial medicine. If you have your rabies injection at the same time as taking your anti-malarial medicine, your rabies vaccine might not work so well.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

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

- before you take Chloroquine phosphate,
- before you take any medicine 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.

- Although Chloroquine phosphate passes into the 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

Sometimes Chloroquine phosphate causes blurred eyesight or makes it difficult to focus your eyes. If this happens to you, do not drive or use any tools or machines.

Chloroquine phosphate Tablets contain Lactose

- If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking these tablets.

Information on Sodium content

- This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. How to take Chloroquine phosphate

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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.**

Adults and children over 14 years

- Take two Chloroquine phosphate tablets once a week on the same day each week.

Elderly people

- If you are an elderly person your doctor may suggest that you have blood tests. Your doctor may also decide to give you a different dose.

Use in Children

Do not give Chloroquine phosphate to children under 1 year of age. For children over 1 year of age, the dose depends on the child's age.

- **Ages 1 to 4 years:** Take half a Chloroquine phosphate tablet once a week (on the same day each week).
- **Ages 5 to 8 years:** Take one Chloroquine phosphate tablet once a week (on the same day each week).
- **Ages 9 to 14 years:** Take one and a half Chloroquine phosphate tablets once a week (on the same day each week).

How to take your tablets

- Take the tablet(s) after food.
- Swallow the tablet(s), or part tablets, whole with a drink of water.

If you take more Chloroquine phosphate tablets than you should

If you take more Chloroquine phosphate tablets than you should, talk to a doctor or go to a hospital straight away. The following effects may happen: heart problems – leading to uneven heart beats.

If you forget to take your Chloroquine phosphate tablets

- If you forget to take a dose of Chloroquine phosphate, take it as soon as you remember.
- Then wait for 7 days before you take the next dose of Chloroquine phosphate.
- Carry on taking your Chloroquine phosphate tablets each week, on this new day of the week.

If you stop taking Chloroquine phosphate

Only stop taking Chloroquine phosphate four weeks after leaving the malaria area or if your doctor tells you to.

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

4. Possible side effects

Like all medicines, Chloroquine phosphate can cause side effects, although not everybody gets them.

Allergic reactions

If you have an allergic reaction, **stop taking Chloroquine phosphate 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 nettle rash or hives).

Other possible side effects

When Chloroquine phosphate is used to prevent or suppress malaria, these are generally not serious. If Chloroquine phosphate is used for a long time, they can be more serious.

Very common:

- Insomnia

Common:

- Depression

Rare:

- Weakening or change in the heart muscle (cardiomyopathy, which is rare). This may make you feel tired or short of breath.
- Liver problems which may cause yellowing of your skin or the whites of your eyes.
- If you are taking Chloroquine phosphate for a long time, your doctor may suggest that you have blood tests to check how well your liver is working.
- Seeing, feeling or hearing things that are not there (hallucinations)
- Cardiac muscle disease (cardiomyopathy) which may be fatal in case of high-dose long-term use. See section 2, warnings and precautions

Not known:

- Blood disorder:
 - A reduced number of blood cells. This can make you bruise more easily, get serious infections, have sudden bleeding or feel very tired or breathless. If you are taking Chloroquine phosphate for a long time, your doctor may suggest that you have blood tests.
- Nervous system:
 - Weakening of your muscles (neuromyopathy and myopathy).
 - Headache. Feeling dizzy or light-headed.
 - Convulsions or fits. Involuntary muscle movements or spasms.
 - Excessive accumulation of phospholipids in tissues
 - Involuntary muscle movements or spasms.
- Psychiatric disorders:
 - Feeling depressed or having thoughts of self-harm or suicide, feeling anxious, feeling confused, having irrational thoughts, paranoia, aggressiveness, sleep disorders, agitation, feeling elated or overexcited, lack of concentration.
- Immune system disorder:
 - A rash caused by the medicine associated with an increase in the number of white blood cells (that may show up in blood tests) and symptoms involving the whole body.
 - You may notice some or all of the following symptoms: a skin rash and fever, swelling of the face, tender generalized swollen or enlarged lymph nodes, or other symptoms suggesting involvement of other body organs including the liver, kidney or lung (such as yellowing of the skin or eyes, urinary problems, breathlessness).
- Metabolism and nutrition disorders:
 - Lowering of the blood glucose level.

- Eye disorders:
 - Blurred eyesight.
 - Some or complete loss of eyesight.
 - Problems with your colour vision.
 - Difficulty in focusing your eyes.
 - Double vision.
 - Changes to the retina of your eye (retinopathy) or to the cornea. This can lead to ‘patchy’ eyesight.

If you are taking Chloroquine phosphate for a long time, your doctor may suggest that you have eye tests.
- Ear and labyrinth disorders:
 - Hearing loss.
 - Ringing in the ears (tinnitus).
- Cardiac disorders:
 - Abnormal heart rhythm, life-threatening irregular heart rhythm (seen on ECG). See section 2, Warnings and precautions.
 - Changes in the way your heart works (known as ‘electrocardiographic changes’).
 - Low blood pressure. This may make you feel faint or dizzy.
- Lung disorders:
 - 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.
- Gastrointestinal Disorders:
 - Stomach upsets, feeling sick (nausea), being sick (vomiting), diarrhoea or stomach cramps.
- Skin Disorders:
 - Skin rash, including a scaly rash (psoriasis) or itch.
 - Peeling skin.
 - A severe rash with blisters or peeling of the skin and possibly blisters in the mouth and nose.
 - Discolouration of the skin or mucous membranes (such as the inside of your mouth).
 - Being sensitive to sun light which may require medical treatment.
 - The appearance of small fluid filled bumps on the skin
- Hair
 - Changes in hair colour.
 - Hair loss.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow card in the Google Play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Chloroquine phosphate

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date (EXP.) which is stated on the label. The expiry date refers to the last day of that month.
- Protect the tablets from light and moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Chloroquine phosphate Tablets contain

Each tablet contains 250 mg of Chloroquine phosphate as an active ingredient.

The other ingredients are lactose, magnesium stearate, Sodium Starch Glycollate, starch and stearic acid.

What Chloroquine phosphate Tablets look like and contents of the pack

Chloroquine phosphate 250 mg tablets are white, uncoated, bi-convex tablets with break-line on one face.

This product is available in blister packs of 10, 12, 20, 24, 30, 36, 40, 48, 50, 60, 70, 72, 80, 84, 90, 96 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Name and address: Bristol Laboratories Ltd,

Unit 3, Canalside, Northbridge Road,
Berkhamsted, Hertfordshire, HP4 1EG,
United Kingdom

Telephone: 0044 (0)1442 200922

Fax: 0044 (0)1442 873717

Email: info@bristol-labs.co.uk

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