

Malarivon Syrup 50mg in 5ml (as base) Oral Solution

Chloroquine Phosphate

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 or risk of contracting malaria 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.

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1. What is Malarivon Syrup and what is it used for?

Malarivon Syrup contains chloroquine phosphate and belongs to a group of medicines called 'anti-malarials'. It acts on the malarial parasite in the blood stream, and may prevent, suppress or treat the disease depending upon the strain of parasite contracted and the progression of the disease.

You must get medical advice on which anti-malarial medicine to take.

When travelling to an area where there is a risk of contracting malaria always consult official guidelines and local information before deciding on which preventative treatment to take. No treatment to prevent malaria is 100% effective.

2. What you need to know before you use Malarivon Syrup?

Do not use:

- ◆ If you are allergic (hypersensitive) to chloroquine phosphate or any of the ingredients listed in section 6 of this leaflet
- ◆ If you are taking a medicine called amiodarone (used to control the heart rate). Malarivon Syrup may increase the risk of uneven heart beats (cardiac arrhythmias) when it is taken at the same time as amiodarone.

Warnings and precautions

Talk to your doctor or pharmacist before taking Malarivon Syrup if:

- ◆ You have any disease of the liver
- ◆ You suffer from any blood disorders (including porphyria, an inherited disease resulting in abnormalities in the normal production of healthy blood)
- ◆ You suffer from kidney problems
- ◆ You suffer from epilepsy, convulsions or diseases of the nervous system
- ◆ You suffer from psoriasis (a skin condition)
- ◆ You suffer from a severe disease of the digestive system
- ◆ You have an inherited condition of glucose-6 phosphate dehydrogenase deficiency such as favism.

Some people being treated with Malarivon Syrup 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.

Long term treatment with Malarivon Syrup should be under medical supervision and your doctor will monitor your eyesight and perform blood tests for you. If you experience any visual disturbances other than a temporary inability to focus at the start of treatment then stop taking the medicine immediately and seek the advice of your doctor.

Taking Malarivon Syrup can result in severe reductions of blood sugar levels. In extreme cases this may result in loss of consciousness. If you notice symptoms that may be related to low blood sugar levels such as shakiness, heart palpitations, poor muscle coordination, pins & needles, slurred speech, dizziness and/or light headedness then consult your doctor.

Other medicines and Malarivon Syrup?

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor or pharmacist if you are taking any of the following medicines. This is because Malarivon Syrup 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 treat epilepsy to prevent convulsions or fits)
- ◆ Digoxin (used to treat heart problems).
- ◆ Azithromycin, 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:

- ◆ Treatments for irregular heart beat
- ◆ Medicines which may cause irregular heart beat as a side effects such as moxifloxacin and droperidol
- ◆ 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 Malarivon Syrup
- ◆ Medicines that may prevent the kidneys from clearing chloroquine from the blood at the normal rate and as a consequence can cause an overdose. The main examples are ciprofloxacin (an antibiotic), cimetidine and omeprazole (used to treat excess stomach acid), and pyrimethamine (used to treat protozoal infections including malaria)
- ◆ Medicines like kaolin (used for diarrhoea) which are called 'adsorbents'
- ◆ Antacid medicines (aluminium, calcium and magnesium salts that are used to treat heartburn or indigestion).

Antacids and adsorbents used to treat heartburn or indigestion can interfere with the absorption of chloroquine so they should not be taken within four hours before or after taking Malarivon Syrup.

Malarivon Syrup can make the symptoms of 'myasthenia gravis' (which causes muscle weakness) more severe and as a consequence reduce the effectiveness of drugs such as neostigmine and pyridostigmine used to treat the condition.

When Malarivon Syrup is taken at the same time as rabies vaccination it may affect the protection provided by the vaccine.

Malarivon Syrup inactivates oral typhoid vaccine, so the vaccine should be taken at least three days before starting a course of Malarivon Syrup.

Pregnancy and breast-feeding?

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.

There are risks to both the mother and the foetus associated with travelling to countries with malaria when pregnant. Always consult a doctor or pharmacist before travelling.

Breast feeding while taking Malarivon Syrup is safe but the small amount of the active ingredient expressed in the milk is not enough to protect the infant 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

When starting treatment with Malarivon Syrup it is possible that you may have blurred or double vision which will make driving and operating machinery unsafe. If you experience such effects then do not drive or operate machinery.

Important information about some of the ingredients in Malarivon Syrup

In addition to the active ingredient, some of the other ingredients in Malarivon Syrup may affect some individuals:

- ◆ Malarivon Syrup contains 2.2g of sucrose in 5ml (13.2g in 30ml); which should be taken into account in patients with diabetes mellitus
- ◆ Para-hydroxybenzoates may cause allergic reactions (possibly delayed)
- ◆ The colouring ponceau 4R (E124) may cause allergic reactions.
- ◆ This medicine contains 695mg propylene glycol in each 5ml. If your child or baby is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, particularly if they use other medicines that contain propylene glycol or alcohol. If you are pregnant or breast-feeding, or if you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

3. How to use Malarivon Syrup?

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Read these instructions carefully because the dose depends both on age and the reason for treatment.

Table 1

Age Group	Dose
Children up to 1 year	2.5ml to 5.0ml
1 to 3 years	7.5ml to 10ml
3 to 6 years	10ml to 15ml
6 to 9 years	15ml to 22.5ml
9 to 12 years	22.5ml to 30ml
Over 12 years including adults	30ml

In the following directions, unless you have been told by a doctor that you are partially immune to malaria, assume that you are **non-immune** and select the appropriate dose.

Suppression or prevention of malaria in non-immune users

Take one dose a week as shown in Table 1. Begin two weeks before entering the malaria area and continue for four weeks after leaving the malaria area.

Suppression or prevention of malaria in partially immune users

Once every two weeks take half the dose shown in Table 1. This will afford a high degree of protection against non-resistant malaria.

Treatment of malaria in non-immune users

Firstly take twice the dose in Table 1. Then, six hours later, take the dose as stated in Table 1. Then, for the next two days, take the dose as stated in Table 1.

Treatment of malaria in partially immune users

Once only, take twice the dose in Table 1.

If you take more Malarivon Syrup than you should

If you have taken a possible overdose then you should seek medical advice immediately. If possible you should take any remaining medicine, packaging and this leaflet with you provided it doesn't cause a delay.

If you forget to take Malarivon Syrup

Do not take a double dose to make up for a forgotten dose. If a dose is missed then resume the treatment immediately. If the product was being taken for prevention of Malaria then be especially alert for any flu like symptoms in the months following and report them immediately to your doctor.

4. Possible side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Malarivon Syrup and see a doctor or go to a hospital straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

Common (affects 1 to 10 people in a 100 people):

- ◆ You have an allergic reaction. The signs may include: red and lumpy skin rash, swollen eyelids, face, lips, mouth or tongue, itching, difficulty breathing or swallowing
- ◆ Fits (convulsions). These could be a sign of malaria in the brain.

Uncommon (affects 1 to 10 people in a 1,000):

- ◆ Uneven heartbeats with or without breathlessness, swollen feet, ankles or legs and tiredness. These could be signs of your heart not beating or working properly. It can further result in heart failure and in some cases with fatal outcome during long term therapy at high doses.

Rare (affects less than 1 in 1000 people):

- ◆ You have severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body
- ◆ Also a feeling of being generally unwell, fever, chills and aching muscles. These could be signs of a serious skin problem
- ◆ You may get infections more easily than usual or feel tired, faint, dizzy or have pale skin. These could be signs of a serious blood problem.

Frequency not known:

- ◆ Problems controlling certain muscles of the body or you have muscle spasms or 'jerks'. The affected muscles may include your tongue, mouth, jaw, arms and legs. The spasms may cause unusual movements of the face, tongue, eyes, neck and affect speech, expression and/or lead to unnatural positioning of the head and shoulders.

Tell your doctor as soon as possible if you have any of the following side effects:

- ◆ Very Common (affects more than 1 in 10 people):
- ◆ Feeling sick or being sick, diarrhoea
- ◆ Headache
- ◆ Itching
- ◆ Tingling, burning or very sensitive skin, muscle weakness, cramps or balance problems. These could be signs of problems with your nerves or muscles
- ◆ Hair loss
- ◆ Darkening of the nails and mucus membranes (lips, mouth, genitals, anus and inner lids of eyes) if Malarivon is taken for a long time.
- ◆ Unable to sleep (insomnia).

Common (affects 1 to 10 people in a 100):

- ◆ Blurred vision that lasts longer than 48 hours. This could lead to permanent damage to your eyes
- ◆ Feeling depressed (depression).

Uncommon (affects 1 to 10 people in a 1,000):

- ◆ Hearing problems and ringing in the ears.

Rare (affects less than 1 in a 1000 people):

- ◆ Loss of eyesight during long term high dose treatment
- ◆ Feeling anxious or confused, being unable to concentrate or seeing or hearing unusual sights

and sounds

- ◆ Yellow colouring of the skin and whites of eyes (jaundice), stomach pain or tenderness. These may be signs of problems with your liver. Tests may reveal changes in the way your liver is working
- ◆ Your psoriasis gets worse.

Frequency unknown:

- ◆ Lowering of the blood glucose level (hypoglycaemia), frequency unknown. You may feel a sense of nervousness, shaky or sweaty. Changes in your eyesight including double vision, eye colour changes, difficulty in focusing, changes to the colours you see or worsening eyesight. In some cases, blindness can happen
- ◆ Stomach cramps
- ◆ Feeling dizzy, light-headed and faint. This could be due to low blood pressure
- ◆ Skin that is itchy, lightens in colour or is more sensitive to sunlight.
- ◆ 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.

Reporting of side effects.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can report side effects directly via the Yellow Card Scheme at 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 Malarivon Syrup?

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the bottle.

Store below 30°C. Protect from light.

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 Malarivon Syrup contains:

The active substance is chloroquine phosphate. Each 5ml of the syrup contains 80mg of chloroquine phosphate which is equivalent to 50mg of chloroquine base. The other ingredients are sucrose, methyl, ethyl, propyl and butyl parahydroxybenzoates, propylene glycol, buttermint toffee essence, sodium saccharin, glycerol, ponceau 4R (E124) and purified water.

What Malarivon Syrup looks like and contents of the pack:

Malarivon Syrup is a clear red syrup supplied in glass bottles of 75ml.

Marketing Authorisation Holder and Manufacturer:

The marketing authorisation owner is:
Wallace Manufacturing Chemists Ltd.,
51-53 Stert Street, Abingdon,
Oxfordshire OX14 3JF, UK.

The manufacturer is:

Laleham Health and Beauty Ltd.,
Bradshaw Lane, Greenhalgh,
Kirkham, Lancashire PR4 3JA, UK.

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