

INFORMATION FOR THE PATIENT

APO-HYDROXYQUINE

Hydroxychloroquine Sulfate Tablets USP

Hydroxychloroquine (hye -drox-ee-KLOR-oh-kwin) belongs to the family of medicines called antimalarials.

This medicine is used to prevent and to treat mosquito-generated malaria infection which is contracted in tropical countries. It is also used in the treatment of arthritis to help relieve inflammation, swelling, stiffness, and joint pain and to help control the symptoms of lupus erythematosus (lupus; SLE).

This medicine may be given alone or with one or more other medicines.

Hydroxychloroquine is available only with your doctor's prescription.

BEFORE USING THIS MEDICINE

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For hydroxychloroquine, the following should be considered:

Allergies -- Tell your doctor if you have ever had any unusual or allergic reaction to hydroxychloroquine or chloroquine. Also tell your health care professional if you are allergic to any other substances, such as foods, preservatives, or dyes.

Pregnancy -- Unless you are taking it for malaria, use of this medicine is not recommended during pregnancy. In animal studies, hydroxychloroquine has been shown to cause damage to the central nervous system (brain and spinal cord) of the fetus, including damage to hearing and sense of balance, bleeding inside the eyes, and other eye problems. However, when given in low doses (once a week) to prevent malaria, this medicine has not been shown to cause birth defects or other problems in pregnant women.

Breast-feeding -- A very small amount of hydroxychloroquine passes into the breast milk. It has not been reported to cause problems in nursing babies to date. However, babies and children are especially sensitive to the effects of hydroxychloroquine.

Children -- Children are especially sensitive to the effects of hydroxychloroquine. This may increase the chance of side effects during treatment. Overdose is especially dangerous in children. Taking as few as 3 or 4 tablets (250-milligrams [mg] strength) of chloroquine has resulted in death in small children. Because hydroxychloroquine is so similar to chloroquine, it is probably just as toxic.

Older adults -- Many medicines have not been studied specifically in older people. Therefore, it may not be known whether they work exactly the same way they do in younger adults or if they cause different side effects or problems in older people. There is no specific information comparing use of hydroxychloroquine in the elderly with use in other age groups.

Other medicines -- Although certain medicines should not be used together at all, in other cases 2 different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. Tell your health care professional if you are taking any other prescription or non prescription (over-the-counter [OTC]) medicine.

Other medical problems -- The presence of other medical problems may affect the use of hydroxychloroquine. Make sure you tell your doctor if you have any other medical problems, especially:

- Blood disease (severe) - Hydroxychloroquine may cause blood disorders;
- Eye or vision problems - Hydroxychloroquine may cause serious eye side effects, especially in high doses;
- Glucose-6-phosphate dehydrogenase (G6PD) deficiency - Hydroxychloroquine may cause serious blood side effects in patients with this deficiency;
- Kidney disease - There may be an increased chance of side effects in patients with kidney disease;
- Liver disease - May decrease the removal of hydroxychloroquine from the blood, increasing the chance of side effects;
- Nerve or brain disease (severe), including convulsions (seizures) - Hydroxychloroquine may cause muscle weakness and, in high doses, seizures;
- Porphyria - Hydroxychloroquine may worsen the symptoms of porphyria;
- Psoriasis - Hydroxychloroquine may bring on severe attacks of psoriasis;
- Stomach or intestinal disease (severe) - Hydroxychloroquine may cause dyspepsia or stomach upset.

PROPER USE OF THIS MEDICINE

Take this medicine with meals or milk to lessen possible stomach upset, unless otherwise directed by your doctor.

Keep this medicine out of the reach of children to avoid accidental poisoning.

It is very important that you take this medicine only as directed. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered. To do so may increase the chance of serious side effects.

If you are taking this medicine to help keep you from getting malaria, keep taking it for the full time of treatment. If you already have malaria, you should still keep taking this medicine for the full time of treatment even if you begin to feel better after a few days. This will help to clear up your infection completely. If you stop taking this medicine too soon, your symptoms may return.

Do not give this medication to anyone else and use it as an antimalarial only for the trip for which it has been prescribed.

Hydroxychloroquine works best when you take it on a regular schedule. For example, if you are to take it once a week to prevent malaria, it is best to take it on the same day each week. Or if you are to take 2 doses a day, 1 dose may be taken with breakfast and the other with the evening meal. Make sure that you do not miss any doses. If you have any questions about this, check with your health care professional.

Dosing -- The dose of hydroxychloroquine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of hydroxychloroquine sulfate. If your dose is different, do not change it unless your doctor tells you to do so.

The number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are taking hydroxychloroquine.

For prevention of malaria:

- Adults -- 400 milligrams (mg) of hydroxychloroquine sulfate once every seven days.
- Children -- Dose is based on body weight and must be determined by your doctor. The usual dose is 6.5 mg per kilogram (kg) (2.9 mg per pound) of body weight once every seven days.

For treatment of malaria:

- Adults -- 800 mg as a single dose. This may sometimes be followed by a dose of 400 mg six to eight hours after the first dose, then 400 mg once a day on the second and third days.
- Children -- Dose is based on body weight and must be determined by your doctor. The usual dose is 32.3 mg per kg (14.6 mg per pound) of body weight taken over a period of three days.

For treatment of lupus erythematosus:

- Adults -- The average initial dose is 400 mg once or twice daily.

For treatment of rheumatoid arthritis:

- Adults -- The usual initial dose is 400 - 600 mg per day.

Missed dose -- If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

For patients taking hydroxychloroquine to prevent malaria:

- Your doctor may want you to start taking this medicine 1 to 2 weeks before you travel to an area where there is a chance of getting malaria. This will help you to see how you react to the medicine. Also, it will allow time for your doctor to change to another medicine if you have a reaction to this medicine.
- Also, you should keep taking this medicine while you are in the area with malaria and for an additional 8 weeks after you leave the area because the malaria parasite has a complex life cycle and may persist for some time in your body. No medicine will protect you completely from malaria. However, to protect you as completely as possible, it is important to keep taking this medicine for the full time your doctor ordered. Also, if fever develops during your travels or within 2 months after you leave the area, check with your doctor immediately.

For patients taking hydroxychloroquine for arthritis or lupus:

- This medicine must be taken regularly as ordered by your doctor in order for it to help you. It may take several months before you feel the full benefit of this medicine.

STORAGE -- To store this medicine:

- Keep out of the reach of children. Overdose of hydroxychloroquine is very dangerous in children.
- Store at controlled room temperature (15-30°C).
- Do not store in the bathroom, near the kitchen sink, or in other damp places.
- Do not keep outdated medicine or medicine no longer needed. Be sure that any discarded medicine is out of the reach of children.

PRECAUTIONS WHILE USING THIS MEDICINE

Check with your doctor immediately if blurred vision, difficulty in reading, or any other change in vision occurs during or after long-term treatment. Your doctor may want you to have your eyes checked by an ophthalmologist (eye doctor).

If your symptoms do not improve within a few days (or a few weeks or months for arthritis), or if they become worse, check with your doctor.

Hydroxychloroquine may cause blurred vision, difficulty in reading, or other change in vision. It may also cause some people to become dizzy or lightheaded. Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are dizzy or are not alert or able to see well. If these reactions are especially bothersome, check with your doctor.

Malaria is spread by mosquitoes. If you are living in, or will be traveling to, an area where there is a chance of getting malaria, the following mosquito-control measures will help to prevent infection:

- If possible, sleep under mosquito netting to avoid being bitten by malaria-carrying mosquitoes.
- Wear long-sleeved shirts or blouses and long trousers to protect your arms and legs, especially from dusk through dawn when mosquitoes are out.
- Apply mosquito repellent to uncovered areas of the skin from dusk through dawn when mosquitoes are out.

SIDE EFFECTS OF THIS MEDICINE

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention. When this medicine is used for short periods of time, side effects usually are rare. However, when it is used for a long time and/or in high doses, side effects are more likely to occur and may be serious.

Check with your doctor immediately if any of the following side effects occur:

Less common: Blurred vision or any other change in vision - this side effect may also occur or get worse after you stop taking this medicine;

Rare: Convulsions (seizures); increased muscle weakness; mood or other mental changes; ringing or buzzing ears or any loss of hearing; sore throat and fever, unusual bleeding or bruising; unusual tiredness, weakness;

Symptoms of overdose: Drowsiness; headache; increased excitability.

Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of the following side effects continue or are bothersome:

More common: Diarrhea; difficulty in seeing to read; headache; itching (more common in black patients); loss of appetite, nausea or vomiting; stomach cramps or pain;

Less common: Bleaching of hair or increased hair loss; blue-black discoloration of skin, fingernails, or inside of mouth; dizziness or lightheadedness; nervousness or restlessness; skin rash.

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with doctor.

WHO MANUFACTURES APO-HYDROXYQUINE

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REMEDERS:

This medicine has been prescribed only for you. Do not give it to anybody else.

If you require any further information or advice please consult your doctor or pharmacist.

