

**Alert - June 15, 2020:** Based on FDA's continued review of the scientific evidence available for hydroxychloroquine sulfate (HCQ) and chloroquine phosphate (CQ) to treat COVID-19, FDA has determined that the statutory criteria for EUA as outlined in Section 564(c)(2) of the Food, Drug, and Cosmetic Act are no longer met. Specifically, FDA has determined that CQ and HCQ are unlikely to be effective in treating COVID-19 for the authorized uses in the EUA. Additionally, in light of ongoing [serious cardiac adverse events](#) and other serious side effects, the known and potential benefits of CQ and HCQ no longer outweigh the known and potential risks for the authorized use. This warrants [revocation of the EUA](#) for HCQ and CQ for the treatment of COVID-19

## **FACT SHEET FOR PATIENTS AND PARENT/CAREGIVERS EMERGENCY USE AUTHORIZATION (EUA) OF HYDROXYCHLOROQUINE SULFATE FOR TREATMENT OF COVID-19 IN CERTAIN HOSPITALIZED PATIENTS**

You are being given hydroxychloroquine sulfate to treat COVID-19. This fact sheet contains information to help you understand the risks and benefits of taking the hydroxychloroquine sulfate you have received or may receive.

There is no U.S. Food and Drug Administration (FDA) approved product available to treat COVID-19. Taking hydroxychloroquine sulfate may benefit certain patients hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible. Read this Fact Sheet for information about hydroxychloroquine sulfate. Talk to your health care provider if you have questions. It is your choice to take hydroxychloroquine sulfate or stop it at any time.

### **WHAT IS COVID-19?**

COVID-19 is caused by a virus called a coronavirus. This type of coronavirus has not been seen before. This new virus was first found in people in Wuhan, Hubei Province, China in December 2019. Person-to-person spread was subsequently reported outside Hubei and in countries outside China, including in the United States. You can get COVID-19 through contact with another person who has the virus.

### **WHAT ARE THE SYMPTOMS OF COVID-19?**

The symptoms are fever, cough and shortness of breath, which may appear 2-14 days after exposure. If you develop **trouble breathing, persistent pain or pressure in the chest, new confusion or trouble waking up or bluish lips or face, get medical attention immediately.**

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can occur and may cause some of your other medical conditions to become worse. Older people and people of all ages with severe chronic medical

conditions like heart disease, lung disease and diabetes, for example seem to be at higher risk of being hospitalized for COVID-19.

### **WHAT IS HYDROXYCHLOROQUINE SULFATE?**

Hydroxychloroquine sulfate (also known as hydroxychloroquine) is an antimalarial medicine approved in the United States for either prevention or treatment of certain types of malaria, lupus erythematosus, and rheumatoid arthritis.

Hydroxychloroquine sulfate has not been approved for the treatment of COVID-19. It has been used experimentally to treat certain people with COVID-19, including hospitalized patients. Hydroxychloroquine sulfate is being used to try and stop the COVID-19 virus from spreading inside your body. This may help you to get better.

Hydroxychloroquine sulfate is experimental because we do not know if it works for COVID-19. It is not approved by FDA for the treatment of COVID-19, but emergency use has been authorized for adults and adolescents who weigh 50 kg (110 pounds) or more and are hospitalized with COVID-19 if a clinical trial is not available or you are not able to participate in a clinical trial. There is limited information known about the safety and effectiveness (whether this will make you better) of using hydroxychloroquine sulfate for hospitalized patients with COVID-19.

### **WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE I TAKE HYDROXYCHLOROQUINE SULFATE?**

**Tell your healthcare provider if you:**

- Have any allergies, including to hydroxychloroquine sulfate (Plaquenil), chloroquine phosphate, chloroquine hydrochloride (Aralen HCl), or any other drugs containing these medications
- Have kidney or liver disease or hepatitis
- Have diabetes or a history of low blood sugar
- Are pregnant or plan to become pregnant
- Are breast-feeding
- Have any serious illnesses
- Have G-6-PD deficiency, porphyria or other blood disorders, psoriasis, an eye problem involving your retina, have a history of seizures, have a heart condition including heart rhythm problems, or if you drink large amounts of alcohol
- Are taking any medications, especially azithromycin, antacids, cimetidine, insulin and other drugs for diabetes, moxifloxacin, amiodarone or other drugs for heart rhythm problems, any drugs for epilepsy or seizures, ampicillin, cyclosporine, mefloquine, praziquantel, tamoxifen, digoxin, methotrexate, iron products, isoniazid, kaolin, magnesium trisilicate, niacin, rifampin, and vitamins and herbal products.

### **WHO SHOULD GENERALLY NOT TAKE HYDROXYCHLOROQUINE SULFATE?**

Do not take hydroxychloroquine sulfate if you have had a previous reaction to hydroxychloroquine sulfate or chloroquine phosphate, or if you have certain eye problems involving your retina. Tell your healthcare provider about any problems you may have with your eyes.

## **HOW DO I TAKE HYDROXYCHLOROQUINE SULFATE?**

Hydroxychloroquine sulfate is given to you by mouth each day at the suggested dose depending on what your health care provider thinks is best for you. The best dose of hydroxychloroquine sulfate to treat COVID-19 is not known. You will be treated with tablets once a day for four to seven days based on your healthcare provider's judgment.

## **WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF HYDROXYCHLOROQUINE SULFATE?**

The most common side effects reported are stomach pain, nausea, vomiting, and headache. These side effects can often be lessened by taking hydroxychloroquine sulfate with food. Hydroxychloroquine sulfate may also cause itching in some people.

All medicines may have some side effects. Minor side effects, such as nausea, occasional vomiting, or diarrhea, usually do not require stopping the drug. If you cannot tolerate hydroxychloroquine sulfate, or experience **irregular heartbeats, fainting or low blood sugar, convulsions or seizures, yellowing of the eyes, seeing light flashes or streaks, blurred vision, difficulty hearing, ringing in ears, muscle weakness, bleeding or bruising of the skin, mood or mental changes, or hives, talk with your health care provider immediately.**

## **WHAT OTHER TREATMENT CHOICES ARE THERE?**

Like hydroxychloroquine sulfate, FDA has allowed for the emergency use of chloroquine phosphate to treat adults and adolescents weighing 50 kg (110 pounds) or more hospitalized with COVID-19. See [www.cdc.gov/website-here.eua](http://www.cdc.gov/website-here.eua) for information on the emergency use of chloroquine phosphate. Chloroquine phosphate is not approved by FDA to treat COVID-19. In addition, your healthcare provider may talk to you about clinical trials being conducted for drugs for the treatment of COVID-19.

## **WHAT IF I DECIDE NOT TO TAKE HYDROXYCHLOROQUINE SULFATE?**

Whether you decide to take hydroxychloroquine sulfate or not, you may be given other available treatments that may include oxygen, fluids and medications depending on your condition and determined by your doctor. The benefit of hydroxychloroquine sulfate in treatment of COVID-19 has not been proven. Even if you take hydroxychloroquine sulfate exactly as directed to treat COVID-19, there is still a chance you may get sicker or die.

It is your choice to be treated or not with hydroxychloroquine sulfate. You can decide not to get it or stop it at any time. It will not change your regular medical care if you decide not to take it.

## **WHAT SHOULD I AVOID WHILE TAKING HYDROXYCHLOROQUINE SULFATE?**

Some other drugs can interact with hydroxychloroquine sulfate and cause you problems. Tell your doctor what other drugs you are taking, including over the counter medicines and dietary supplements.

## **WHAT IF I AM PREGNANT OR BREASTFEEDING?**

In humans, a small number of studies using hydroxychloroquine sulfate during pregnancy have shown no increase in the rate of birth defects or spontaneous abortions. If you are pregnant or nursing, discuss your options and specific situation with your doctor.

#### **HOW DO I REPORT SIDE EFFECTS WITH HYDROXYCHLOROQUINE SULFATE?**

Call your healthcare provider if you have any side effects that bother you or do not go away. Report side effects to **FDA MedWatch** at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088. Submitted reports should state “use of hydroxychloroquine sulfate was under an EUA”.

#### **HOW SHOULD I STORE HYDROXYCHLOROQUINE SULFATE?**

Hydroxychloroquine sulfate should be stored in childproof containers out of the reach of infants and children. Store in a cool, dry place, at room temperature, away from direct heat and light.

#### **HOW CAN I LEARN MORE?**

- Ask your healthcare provider
- Visit <https://www.cdc.gov/coronavirus/2019-ncov/index.html>
- Contact your local or state public health department

# Revoked