

APO-Hydroxychloroquine

Contains the active ingredient, hydroxychloroquine sulfate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

The name of your medicine is APO-Hydroxychloroquine. It contains the active ingredient hydroxychloroquine sulfate.

It may be used for any of the following conditions:

Rheumatoid Arthritis

Rheumatoid arthritis is a form of arthritis with inflammation of the joints, characterized by stiffness, swelling and pain.

Hydroxychloroquine may be used for short or long-term rheumatoid arthritis treatment.

In treating rheumatoid arthritis, hydroxychloroquine may slow down the process of joint damage and relieve the symptoms of the disease.

Systemic Lupus Erythematosus (SLE)

SLE is a disease in which a person's normal immunity is upset. The body produces an excess of blood proteins called antibodies and these antibodies may cause problems in any organ of the body.

These antibodies may end up, for example, in the skin causing a variety of skin rashes or deposit in the kidney, brain, lung and joints causing injury.

Discoid Lupus Erythematosus (DLE)

DLE is similar to SLE, except it only affects the skin and is characterized by a scaling, red rash.

Malaria (treatment and control of symptoms)

Malaria is an infectious disease caused by the presence of parasites in red blood cells.

The disease is characterized by chills, fever and sweats.

In malaria, hydroxychloroquine destroys the harmful parasite which causes the illness.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed hydroxychloroquine for another reason.

This medicine is available only with a doctor's prescription.

Hydroxychloroquine is not addictive.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- hydroxychloroquine
- chloroquine or related products

- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, asthma attack
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hay fever or hives on the skin

Do not take this medicine if you are pregnant.

Ask your doctor about the risks and benefits of taking this medicine while you are pregnant.

When hydroxychloroquine is taken for long periods of time, there is an increased risk to the unborn child. It may cause problems with brain function, hearing, balance and vision.

Do not breastfeed if you are taking this medicine.

Ask your doctor about the risks and benefits of taking this medicine while you are breastfeeding.

Do not take this medicine if you have previously experienced changes in your eyesight when taking medicines for rheumatoid arthritis or malaria.

Hydroxychloroquine should not be used in children under 6 years.

Hydroxychloroquine should not be used in children over 6 years for long periods.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- an allergy to quinine
- you have allergies to any ingredients listed under product description at the end of this leaflet.
- any pre-existing eye disorders
- low blood sugar levels (hypoglycaemia - a "hypo") - hydroxychloroquine may increase the risk of you having a hypo
- chloroquine-resistant malaria
- liver or kidney problems
- diabetes
- stomach, brain or blood disorders
- disease of the heart muscle
- skin diseases, in particular psoriasis, a type of itchy rash
- Glucose-6-phosphate dehydrogenase (G-6-PD) deficiency, which is a lack of a chemical substance which causes the breakdown of sugar in the body
- porphyria, a rare disease of blood pigments

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and hydroxychloroquine may interfere with each other. These include:

- medicines used to treat depression including the herbal product St John's wort
- antipsychotic medications
- medicines to treat epilepsy, such as carbamazepine and phenobarbital
- medicines to treat diabetes
- digoxin, used to treat heart disease
- anti-arrhythmic drugs which control heart rhythm, such as amiodarone and moxifloxacin
- medicines used to suppress the immune system such as cyclosporin
- moxifloxacin or other anti-infective medicines
- tamoxifen (a medicine used to treat breast cancer)
- Medicines that may affect your blood
- Medicines that may affect your eyes
- Antacids containing magnesium or Kaolin or cimetidine, used to neutralise stomach acid
- Itraconazole, an antifungal medication
- Clarithromycin and rifampicin (antibiotics)
- Grapefruit Juice
- Anticoagulant drugs such as dabigatran and clopidogrel
- Medicines to treat high cholesterol, such as gemfibrozil
- Ritonavir (a medicine used to treat HIV)
- other drugs to treat malaria

These medicines may be affected by hydroxychloroquine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Other interactions not listed above may also occur.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take.

This depends on your condition and whether you are taking any other medicines.

Rheumatoid arthritis

Adults

The usual dosage is 2-3 tablets daily. Your doctor may later reduce this to 1-2 tablets daily.

SLE and DLE

Adults

The usual dosage is 2-4 tablets daily. Your doctor may later reduce this to 1-2 tablets daily.

Control of Malaria Symptoms

Adults

The usual dosage is 2 tablets once a week. The tablets should be taken on exactly the same day of each week.

For example, if your first dose is taken on a Monday, then each weekly dose should be taken on a Monday.

Treatment of Malaria

Adults

The starting dose is 4 tablets. Take another 2 tablets six to eight hours later and a further 2 tablets on each of the next two days.

Always follow the instructions given to you by your doctor.

Dosages for children are calculated according to the child's body weight.

Your doctor will work out the correct dose for children.

Hydroxychloroquine should not be used in children for long periods.

Your doctor may ask you to take a different dose. You should follow the instructions on the label.

If you are unsure what dose to take ask your doctor.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It is best to take hydroxychloroquine at mealtimes.

How long to take it for

Continue taking your medicine for as long as your doctor tells you to.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If you are being given hydroxychloroquine for rheumatoid arthritis or SLE or DLE, do not take a double dose to make up for the dose missed. Just continue with the appropriate dose on the next day.

If you are being given hydroxychloroquine for suppression or treatment of malaria, you should take your tablets as soon as you remember and go back to taking it as you would normally.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much hydroxychloroquine, you may experience headaches, drowsiness, visual disturbances or fits. These symptoms may occur within 30 minutes of overdose.

While you are taking this medicine

Your doctor will need to perform the following tests during treatment with this medicine:

Eye Tests

Your doctor will need to perform some eye tests every few months to check that your eyesight is not changing.

In extremely rare cases, hydroxychloroquine has been associated with blindness. This can be avoided by having regular eye tests.

It is recommended you wear sunglasses when out in the sun.

Blood Tests

Your doctor will need to perform occasional blood tests to check for any blood reactions.

Your doctor may monitor your blood sugar levels if you have experienced hypoglycaemia while taking hydroxychloroquine.

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if you experience any of the following symptoms including:

- weakness
- trembling or shaking
- sweating
- light-headedness
- headache
- dizziness
- lack of concentration
- tearfulness or crying
- irritability
- hunger
- numbness around the lips and fingers

These symptoms may be associated with hypoglycaemia.

Treating hypoglycaemia

If you experience any of the symptoms of hypoglycaemia, you need to raise your blood glucose urgently. You can do this by taking one of the following:

- 5-7 jelly beans
- 3 teaspoons of sugar or honey
- 1/2 can of ordinary (non-diet) soft drink
- 2-3 concentrated glucose tablets

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates e.g. plain biscuits, fruit or milk - when over the initial symptoms.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

Make sure you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and know how to treat them.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking your medicine, or change the dosage, without checking with your doctor.

Things to be careful of

Be careful while driving or operating machinery until you know how hydroxychloroquine affects you.

Hydroxychloroquine may cause problems with the eyesight of some people. Make sure you know how you react to hydroxychloroquine before you drive a car, operate machinery, or do anything else that could be dangerous with blurred vision.

Hydroxychloroquine may cause hypoglycaemia, which can impair your ability to drive or operate machinery.

Make sure you are aware of the symptoms of hypoglycaemia and avoid dangerous activities until your blood sugar returns to normal (see 'Treating hypoglycaemia' under 'Things you must do').

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking hydroxychloroquine.

Hydroxychloroquine helps most people with rheumatoid arthritis, SLE, DLE, treatment of malaria and the control of malaria symptoms, but it may have unwanted side effects in a few people.

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea
- vomiting
- diarrhoea
- abdominal cramps
- loss of appetite
- muscle weakness
- dizziness
- ringing in the ears
- headache
- nervousness
- skin rash and itching
- hair loss

If you already have psoriasis, you are more likely to experience skin reactions than other people when taking hydroxychloroquine.

Tell your doctor as soon as possible if you notice any of the following:

- visual disturbances
- any hearing loss

- frequent fevers, severe chills, bruising, sore throat or mouth ulcers (these may be signs of blood reactions)
- More severe symptoms of hypoglycaemia, including disorientation, seizures, fits or convulsions and loss of consciousness
- nightmares
- abnormal behaviour such as delusions, hallucinations and feeling agitated
- suicidal behaviour
- Changes in the way your heart beats
- movement problems, such uncontrolled movements, stiffness or tremors
- wide spread rash with blisters, with or without fever, which can indicate a severe drug induced allergic reaction. It can involve blood changes and internal organs.

These are serious side effects. You may need medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Other side effects not listed above may occur in some patients.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect from light.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat, sunlight and dampness can destroy some medicines.

Keep it where children cannot reach it.

Children are particularly sensitive to the unwanted effects of hydroxychloroquine.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What APO-Hydroxychloroquine looks like

White to off-white, capsule-shaped tablets, embossed "HCQS" on one side, plain on the other side. AUST R 186393.

Packaged in bottles of 100 tablets.

Ingredients

Each tablet contains 200 mg of hydroxychloroquine sulfate as the active ingredient.

It also contains the following inactive ingredients:

- Calcium hydrogen phosphate
- pregelatinised maize starch
- hypromellose
- magnesium stearate
- polysorbate 80
- colloidal anhydrous silica
- Opadry II White 85F18422.

This medicine is gluten-free, lactose-free and free of other azo dyes.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113
Australia
Tel: (02) 8877 8333
Web: www1.apotex.com/au

APO is a registered trademark of Apotex Inc.

This leaflet was last updated in August 2020.