

HYDROXYCHLOROQUINE GH

(hydroxychloroquine sulfate) tablet

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Hydroxychloroquine GH.

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 using this medicine against the benefits they expect it will have for you.

Keep this leaflet with your medicine.

You may want to read it again.

What Hydroxychloroquine GH is used for

Hydroxychloroquine GH may be used for any of the following conditions.

Rheumatoid Arthritis

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

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

In treating rheumatoid arthritis, Hydroxychloroquine GH 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 characterised 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 characterised by chills, fever and sweats.

In malaria, Hydroxychloroquine GH destroys the harmful parasite which causes the illness.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why

Hydroxychloroquine GH has been prescribed for you.

Hydroxychloroquine GH is not addictive. This medicine is available only with a doctor's prescription.

Before you take Hydroxychloroquine GH

When you must not take it

Do not take this medicine if you have ever had an allergic reaction to:

- hydroxychloroquine, chloroquine or related products;
- any of the ingredients listed under "Product Description".

If you are uncertain whether you have had an allergic reaction to a related product, ask your doctor or pharmacist.

The symptoms of an allergic reaction may include an asthma attack, facial swelling, skin rash or hay fever.

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.

Ask your doctor about the risks and benefits of taking Hydroxychloroquine GH while you are breast-feeding.

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

Hydroxychloroquine GH should not be used in children under 6 years of age.

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

Do not take Hydroxychloroquine GH after the expiry date (EXP) printed on the bottle.

It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not take Hydroxychloroquine GH if the bottle is damaged or shows signs of tampering.

Do not take Hydroxychloroquine GH to treat any other complaint unless your doctor says it is safe.

Do not give this medicine to anyone else.

Before you start to take it

You must tell your doctor if:

- you are taking any other medicines for any medical condition;
- you are allergic to quinine;
- you have allergies to any ingredients listed under "Product Description" at the end of this leaflet;
- you have any pre-existing eye disorders;
- you have experienced low blood sugar levels (hypoglycaemia – a "hypo"). Hydroxychloroquine GH may increase the risk of you having a hypo;
- you have, or have had, any of these medical conditions:
 - chloroquine-resistant malaria,
 - liver or kidney problems,
 - diabetes,
 - stomach, brain or blood disorders,
 - disease of the heart muscle,
 - skin diseases, in particular psoriasis which is a kind 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, which is a rare disease of blood pigments;

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 buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Hydroxychloroquine GH. These include:

- any medicine to treat depression, including the herbal product St John's wort;
- digoxin, flecainide, propafenone – a medicine used to treat heart disease;
- medicines to treat diabetes;
- medicines used to suppress the immune system such as ciclosporin;
- anti-arrhythmic drugs such as amiodarone and moxifloxacin;
- other antimalarial drugs;
- medicines to treat epilepsy, such as carbamazepine and phenobarbital;
- tamoxifen (a medicine used to treat breast cancer);
- anti-infective medicines;
- medicines that may affect your blood;
- medicines that may affect your eyes;
- antacids containing magnesium or kaolin or cimetidine, used to neutralize 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).

These medicines may be affected by Hydroxychloroquine GH or affect the way Hydroxychloroquine GH works.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

How to take Hydroxychloroquine GH

Always follow the instructions that your doctor and pharmacist give you about Hydroxychloroquine GH.

Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

If you have any concerns about taking Hydroxychloroquine GH, ask your doctor or pharmacist.

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 or not you are taking any other medicines.

The dosage will depend on why you are being treated with Hydroxychloroquine GH.

The usual doses are as follows.

Rheumatoid Arthritis

Adults

2-3 tablets daily. Your doctor may later reduce this to 1-2 tablets daily.

SLE and DLE

Adults

2-4 tablets daily. Your doctor may later reduce this to 1-2 tablets daily.

Control of Malaria Symptoms

Adults

2 tablets once a week.

The tablets should be taken at 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 two further tablets on each of the next 2 days.

Always follow the instructions given to you by your doctor.

Children

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

Your doctor will work out the correct dose for you.

Hydroxychloroquine GH 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 pharmacist or doctor.

How to take it

Swallow tablets whole with a little water or other liquid.

When to take it

It is best to take Hydroxychloroquine GH at meal times.

How long to take it

Continue taking your medicine for as long as your doctor tells you. Make sure you have enough to last over weekends and holidays.

If you forget to take it

If you are taking Hydroxychloroquine GH for rheumatoid arthritis, 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 GH 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 (phone 13 11 26 for Australia) for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much Hydroxychloroquine GH.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Hydroxychloroquine GH tablets, you may experience headaches, drowsiness, visual disturbances or fits.

These symptoms may occur within 30 minutes of overdose.

- hunger;
- numbness around the lips or fingers.

These symptoms may be associated with 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 jellybeans;
- 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 eg. 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.

Your doctor will need to perform the following tests during treatment with Hydroxychloroquine GH.

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.

Driving/Operating Machinery

Be careful driving or operating machinery until you know how Hydroxychloroquine GH affects you.

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

Side effects

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

Hydroxychloroquine GH 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 can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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.

Less serious side effects

- stomach problems such as:
 - nausea;
 - vomiting;
 - diarrhoea;
 - abdominal cramps.
- other problems such as:
 - 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 GH.

More serious side effects

- visual disturbances;
- any hearing loss;
- suicidal behaviour;
- having thoughts of self-harm or suicide
- feeling depressed, feeling nervous or anxious, feeling confused, agitated, difficulty sleeping, delusions, hallucinations, changes in mood, feeling elated or overexcited.
- frequent fevers, severe chills, bruising, sore throat or mouth ulcers (these may be signs of blood reactions);
- changes in the way your heart beats;
- liver problems that may cause the eyes or skin to go yellow (jaundice)
- rash with a fever and flulike symptoms and enlarged lymph nodes. This could be a condition called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- blistering, widespread scaly skin, pus-filled spots together with fever. This could be a condition called Acute Generalized Exanthematous Pustulosis (AGEP).
- blistering or peeling of the skin around the lips, eyes, mouth, nose, genitals, hands or feet, flulike symptoms and fever. This could be a condition called Stevens-Johnson syndrome (SJS).
- multiple skin lesions, itching of the skin, joint aches, fever and a general ill feeling. This could be a condition called Toxic Epidermal Necrolysis (TEN).
- skin reaction including reddish purple color, raised, painful sores, particularly on your arms, hands, fingers, face and neck, which may also be accompanied by fever. This could be a

condition called Sweet's syndrome

- more severe symptoms of hypoglycaemia, including:
 - disorientation,
 - seizures, fits or convulsions,
 - loss of consciousness.

These are serious side effects. You may need urgent medical attention.

Serious side effects are rare.

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

Some people may get other side effects while taking Hydroxychloroquine GH.

After taking Hydroxychloroquine GH

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.

Do not leave Hydroxychloroquine GH in a car or on a windowsill.

Do not store Hydroxychloroquine GH, or any other medicine, in the bathroom or near a sink.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Children are particularly sensitive to the unwanted effects of hydroxychloroquine.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask

your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Hydroxychloroquine GH tablets are white to off-white, capsule-shaped tablets, embossed with "HCQS" on one side and plain on the other side.

Hydroxychloroquine GH is available in bottles of 100 tablets.

Ingredients

Active ingredient

Each Hydroxychloroquine GH tablet contains 200 mg of hydroxychloroquine sulfate as the active ingredient (equivalent to 155 mg hydroxychloroquine).

Other ingredients

- calcium hydrogen phosphate;
- pregelatinised maize starch;
- hypromellose;
- magnesium stearate;
- polysorbate 80;
- colloidal anhydrous silica;
- Opadry II complete film-coating system 85F18422 White (PI 11376).

Hydroxychloroquine GH is free from gluten, lactose and other azo dyes.

Australian Registration

Numbers

Hydroxychloroquine GH 200 mg:
AUST R 223695

Sponsor

Generic Health Pty Ltd
Suite 2, Level 2
19-23 Prospect Street
Box Hill, VIC, 3128
Australia

Email:
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Telephone: +61 3 9809 7900

Website:
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Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

This leaflet was prepared in September 2022.