

HCQS TABLET

Hydroxychloroquine Sulfate (200 mg)

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What HCQS Tablet is taken for

HCQS Tablet is used in the treatment of:

1. Rheumatoid arthritis – a condition causing joint pain and swelling.
2. Lupus – an autoimmune disease that can affect the skin (discoid lupus) or the whole body (systemic lupus).

How HCQS Tablet works

HCQS Tablet contains the active ingredient hydroxychloroquine sulfate which is an antirheumatic medication. It works by decreasing the activity of the immune system, subsequently reducing pain, swelling and joint stiffness.

Before you take HCQS Tablet

- When you must not take it

Do not take HCQS Tablet if:

- You are allergic (hypersensitive) to hydroxychloroquine sulfate or 4-aminoquinoline compounds (e.g. chloroquine, amodiaquine) or any other ingredients of this medicine (listed in Product Description).
- You have eye problems (maculopathy).

This medication cannot be used for long term therapy in children.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast feeding before using any medicine.

HCQS may be associated with a small increased risk of malformations and should not be used during pregnancy unless your doctor considers the benefits outweigh the risks. If you could get pregnant while taking HCQS Tablet, a reliable form of contraception should

always be used.

HCQS Tablet is secreted into the breastmilk in small quantity, and due to the risk of side effects in the baby, extra caution needs to be taken during breastfeeding. Seek immediate medical attention if you notice your baby is experiencing any side effects.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking HCQS Tablet.

- Before you start to take it

Take special care and check with your doctor or pharmacist before taking HCQS Tablet if:

- **You have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used for breathing). You may notice aggravation of symptoms such as muscle weakness, difficulty in swallowing, double vision, drooping of the upper eyelid etc.**
- **Hydroxychloroquine may cause heart, kidney or muscle disorders. Please ask your doctor to inform you of signs and symptoms of drug induced phospholipidosis. Hydroxychloroquine may need to be stopped.**
- Liver or kidney problems or taking medications that are known to affect liver and kidney function.
- Serious stomach or gut problems.
- Eye or vision problems.
- Any blood-related problems.
- Sensitive to quinine.
- Certain enzyme deficiencies (like glucose-6-phosphate dehydrogenase deficiency)
- Porphyria (rare inherited disorders)
- Psoriasis (skin condition that causes flaky patches of skin).

Taking other medicines

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

Tell your doctor if you are taking:

- Digoxin (used for heart failure and irregular heartbeats)
- Cyclosporin (used to prevent rejection after organ transplant)
- Neostigmine, pyridostigmine (used

for muscle weakness in myasthenia gravis)

- Aminoglycoside antibiotics (used for bacterial infections)
- Antacids, cimetidine (used for digestion problems or acid reflux)
- Penicillamine (used for rheumatoid arthritis and Wilson's disease).
- Rabies vaccine (used for rabies prevention).

How to take HCQS Tablet

Always take your medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- How much to take

Your doctor will prescribe the dose depending on your body weight. Please consult your doctor for the exact dosage to be taken.

Adults (including the elderly):

- 1 or 2 tablets each day.
- The dose can be reduced from 2 tablets to 1 tablet daily when there is no further improvement.

Children weighing more than 31kg and able to swallow tablet:

- 1 tablet each day.

- When to take it

Take once or twice daily, or as directed by your doctor or pharmacist.

Take each dose with food or a glass of milk. Avoid taking antacids within four hours of hydroxychloroquine, as they can reduce its effectiveness.

- How long to take it

Take HCQS Tablet for the duration that the doctor recommends.

Full effects may take a few weeks, and if there is no improvement after six months, see your doctor again.

- If you forget to take it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else

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may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause severe headache, sudden changes in vision, rapid heartbeat, fainting, or a racing heart. Seizures or uncontrolled shaking and difficulty breathing or feeling unable to catch your breath may also occur.

While you are taking it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking HCQS Tablet.

Tell your doctor immediately if you become pregnant while using this medication.

Take HCQS Tablet only with a doctor's prescription.

- Things you must not do

Do not stop taking your medicines unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give this medication to anyone else, even if they have the same condition as you.

- Things to be careful of

Driving and using machines.

If the medicine affects your vision, do not drive or use machines, and tell your doctor straight away.

Your doctor will perform regular eye exams, as this medicine can affect vision over time, especially with long-term use.

Watch out for any mood changes, such as unusual sadness for thoughts of self-harm, particularly in the first few weeks of taking this medication.

Protect your skin from sunlight, as hydroxychloroquine can make it more sensitive to light.

Keep medicine out of reach of children, as it can be highly toxic to them even in

small amounts.

Side effects

Like all medicines, HCQS Tablet can cause side effects although not everybody gets them.

Psychiatric disorders

- Common: mood swings.
- Uncommon: nervousness.
- Frequency not known: feeling depressed or having thoughts of self-harm or suicide, feeling nervous or anxious, feeling confused, hallucinations, agitated, feeling elated or overexcited, difficulty sleeping.

Skin and subcutaneous tissue disorders

- Skin rashes, changes in skin color, hair loss, or lightening of hair color.
- Rare cases of severe skin reactions.
- May worsen certain skin conditions like psoriasis or porphyria.
- Frequency not known: Skin reaction including plum-colored, 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.

Eye disorders

- May affect vision, but reversible in early stages if the drug is stopped.
- Corneal changes: swelling or cloudiness in the eye, which might cause vision issues like halos, blurred vision, or light sensitivity, but reversible when stopping the drug.

Gastrointestinal disorders

- Common: nausea, diarrhea, loss of appetite, stomach cramps, sometimes vomiting.
- Rare: liver issues, including liver failure.

Central nervous system disorders

- Irritability, nervousness, emotional changes, nightmares, psychosis, headaches, dizziness, vertigo, ringing in the ears, vision issues, hearing loss, seizures, difficulty with balance.

Neuromuscular disorders

- Muscle weakness, muscle pain, or nerve-related issues that can lead to weakness and muscle wasting, especially in the upper legs and arms.

Blood disorders

- Blood issues such as low red or white

blood cells or platelets, and a risk of severe reactions in people with a specific enzyme deficiency (G6PD deficiency).

Other side effects:

- Weight loss, fatigue, worsening of certain skin conditions, and rarely heart problems (especially with high doses).
- **Accumulation of a type of fat in tissues causing harm. The doctor may decide to stop the treatment with HCQS Tablet**

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed in this leaflet may also occur in some patients.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of HCQS Tablet

- Storage

Store below 30°C in a dry place. Keep this medicine out of the sight and reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

HCQS Tablet is white, circular, biconvex film-coated tablet.

- Ingredients

- Active ingredient

Hydroxychloroquine sulfate
200 mg

- Inactive ingredients

Tablet core: Magnesium stearate, calcium hydrogen phosphate dihydrate, maize starch, colloidal anhydrous silica, purified talcum, purified water BP, polysorbate 80, colloidal anhydrous silica.

Film coating: Polyethylene glycol 6000, titanium dioxide, purified talcum, hydroxy propyl methyl cellulose.

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- MAL Number

MAL11080003AZ

Manufacturer

Ipca Laboratories Ltd.
Plot No. 255/1, Village-Athal,
Silvassa 3962360, Union
Territory of Dadra & Nagra
Haveli and Daman & Diu, India

Product Registration Holder

The Zyfas Medical Co.
No. 15, Jalan Mega 1/5
Taman Perindustrian Nusa Cemerlang
79200 Iskandar Puteri, Johor
Malaysia

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