

# Hydroxychloroquine AN

(Hydroxychloroquine Sulfate 200 mg Film Coated Tablets)

## Consumer Medicine Information

### What Is In This Leaflet

**Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.**

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

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

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 AN Is Used For

The name of your medicine is Hydroxychloroquine AN. 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.

Your doctor may have prescribed hydroxychloroquine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Hydroxychloroquine is not addictive. This medicine is available only with a doctor's prescription.

### Before You Take Hydroxychloroquine AN

#### *When you must not take it*

**Do not take this medicine if you have had an allergic reaction to hydroxychloroquine, chloroquine or related products or any of the ingredients listed at the end of this leaflet. If you are uncertain whether you have had an allergic reaction to a related product ask your doctor or pharmacist.**

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 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 (EXP) printed on the pack.**

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

**Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.**

**Do not take this medicine 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:**

1. You are allergic to quinine.
2. You have allergies to any ingredients listed under "Product Description" at the end of this leaflet.
3. You have any pre-existing eye disorders.
4. You have experienced low blood sugar levels (hypoglycaemia - a "hypo"). Hydroxychloroquine may increase the risk of you having a hypo.
5. 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.
6. You plan to become pregnant or breast-feed.

**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 and hydroxychloroquine may interfere with each other. These include:

- Any medicine to treat depression
- Digoxin - a medicine used to treat heart disease
- Medicines to treat diabetes
- Medicines used to suppress the immune system such as cyclosporine
- Antiarrhythmic drugs such as amiodarone
- Other antimalarial drugs
- Medicines to treat epilepsy

These medicines may be affected by hydroxychloroquine or may affect how well it works.

Your doctor and pharmacist can tell you if you are taking any of these medicines.

### How To Take Hydroxychloroquine AN

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

**Swallow tablets whole with a little water or other liquid.**

It is best to take it at meal times.

#### *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.

The usual doses are:

#### *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 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 two further tablets on each of the next 2 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 you.

**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 pharmacist or doctor.**

*How long to take it for*

**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 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 (Tel: 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. 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.

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## While You Are Taking Hydroxychloroquine AN

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**If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking hydroxychloroquine.**

**Tell all doctors, dentists and pharmacists who are treating you that you are taking hydroxychloroquine.**

**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 and numbness around the lips and 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 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 recognize the symptoms of hypoglycaemia and know how to treat them. Your doctor will need to perform the following tests during treatment with hydroxychloroquine:

### 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 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.

### Things you must do

**Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Hydroxychloroquine.**

**Tell your doctor immediately if you become pregnant.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.**

**Go to your doctor regularly for a check-up.**

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

### 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.

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## Side Effects of Hydroxychloroquine AN

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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.

**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.

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.**

Following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

**Tell your doctor or pharmacist 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.

### More serious side effects

**Tell your doctor if you notice any of the following:**

- Visual disturbances
- Any hearing loss
- Suicidal behaviour
- 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
  - loss of consciousness

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

Serious side effects are 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.**

Some people may get other side effects while taking hydroxychloroquine.

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## After Using Hydroxychloroquine AN

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### *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.**

Heat and dampness can destroy some medicines.

**Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill 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 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.**

### *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.

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## Product Description

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### *What Hydroxychloroquine AN Tablets looks like?*

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

Packaged in bottles of 100 tablets.

### *Ingredients*

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

It also contains the following inactive ingredients:

- anhydrous 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.

### *Australian Registration Numbers*

Hydroxychloroquine AN: 223694

### *Sponsor*

**Amneal Pharma Australia Pty Ltd**

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