

Plaquenil Tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Plaquenil?

Plaquenil contains the active ingredient hydroxychloroquine sulfate. Plaquenil is used to treat rheumatoid arthritis and may slow down the process of joint damage and relieve the symptoms of the disease. For more information, see Section [1. Why am I using Plaquenil?](#) in the full CMI.

2. What should I know before I use Plaquenil?

Do not use if you have ever had an allergic reaction to hydroxychloroquine sulfate or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Plaquenil?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Plaquenil and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Plaquenil?

- Swallow tablets whole with a little water or other liquid at mealtimes. The dosage will depend on why you are being treated with Plaquenil. More instructions can be found in Section [4. How do I use Plaquenil?](#) in the full CMI.

5. What should I know while using Plaquenil?

| | |
|----------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Plaquenil. |
| Things you should not do | <ul style="list-style-type: none">• Plaquenil should not be used in children under 6 years.• Plaquenil should not be used in children over 6 years for long periods. |
| Driving or using machines | <ul style="list-style-type: none">• Plaquenil may cause problems with the |

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|---|---|
| | <p>eyesight of some people. Make sure you know how you react to Plaquenil before you drive a car, operate machinery, or do anything else that could be dangerous with blurred vision.</p> |
| <p>Looking after your medicine</p> | <ul style="list-style-type: none"> ● Keep your tablets in the bottle until it is time to take them. ● If you take the tablets out of the bottle they will not keep well. ● Keep it in a cool dry place where the temperature stays below 25°C. |

For more information, see Section [5. What should I know while using Plaquenil?](#) in the full CMI.

6. Are there any side effects?

Speak to your doctor if you have any of these less serious side effects 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. Call your doctor straight away or go to the Emergency Department at your nearest hospital if you have any of

these serious side effects: visual disturbances, hearing loss, suicidal behavior, frequent fevers, severe chills, bruising, sore throat or mouth ulcers (these may be signs of blood reactions), changes in the way your heart beats. 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. Liver problems. Symptoms may include a general feeling of being unwell, with or without jaundice (yellowing of the skin and eyes), dark urine, nausea, vomiting and/or abdominal pain. Rare cases of liver failure (including fatal cases) have been observed. Kidney problems due to accumulation of phospholipids. More severe symptoms of low blood sugar levels including disorientation, seizures, fits or convulsions and loss of consciousness. Rash with a fever and flu-like symptoms and enlarged lymph nodes. Blistering, scaly skin, pus-filled spots with fever. Blistering or peeling of the skin with flu-like symptoms and fever. Skin lesions, skin itching, joint aches, fever and a general ill feeling. Reddish-purple coloured painful sores with or without a fever. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Plaquenil Tablets

Active ingredient(s): *hydroxychloroquine sulfate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Plaquenil. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Plaquenil.**

Where to find information in this leaflet:

- [1. Why am I using Plaquenil?](#)
- [2. What should I know before I use Plaquenil?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Plaquenil?](#)
- [5. What should I know while using Plaquenil?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Plaquenil?

Plaquenil contains the active ingredient hydroxychloroquine sulfate.

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

In treating rheumatoid arthritis, Plaquenil 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, Plaquenil 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 Plaquenil has been prescribed for you.

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

2. What should I know before I use Plaquenil?

Warnings

Do not use Plaquenil if:

- you are allergic to hydroxychloroquine, chloroquine or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You have previously experienced changes in your eyesight when taking medicines for rheumatoid arthritis or malaria.
- You have a heart rhythm disorder.
- Plaquenil should not be used in children under 6 years.
- Plaquenil should not be used in children over 6 years for long periods.
- Do not take Plaquenil after the expiry date printed on the bottle.
- Do not take Plaquenil if the bottle is damaged or shows signs of tampering.

- Do not take Plaquenil to treat any other complaint unless your doctor says it is safe. Do not give this medicine to anyone else.

Check with your doctor if you:

- are taking any other medicines for any medical condition.
- are allergic to quinine.
- have allergies to any ingredients listed under "Product Description" at the end of this leaflet.
- have any pre-existing eye disorders.
- have experienced low blood sugar levels (hypoglycaemia - a "hypo"). Plaquenil may increase the risk of you having a hypo.
- have an inactive chronic infection such as hepatitis B, chickenpox/shingles (a painful blistering rash) or tuberculosis as they may flare up.
- 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

- Porphyria Cutanea Tarda (PCT), which is a rare disorder of painful, blisters on the skin
- 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, etc.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Plaquenil should be avoided in pregnancy except when, in the judgement of the physician, the potential benefits outweigh the potential hazards.

When Plaquenil 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.

There is very limited data on the safety in the breastfed infant during long-term treatment with Plaquenil. The active ingredient (hydroxychloroquine) is excreted in breast milk and it is known that infants are extremely sensitive to the toxic effects.

Plaquenil should not be used during breast-feeding unless your doctor considers the benefits outweigh the risks.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or think you may be pregnant or planning to have a baby or breast-feeding. Your doctor will discuss with you whether Plaquenil is suitable for you.

3. What if I am taking other medicines?

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

Some medicines may interfere with Plaquenil and affect how it works, these include:

- Any medicine to treat depression, including fluoxetine, paroxetine, and the herbal product St John's wort
- Digoxin, Flecainide, Propafenone, Quinidine - medicine used to treat heart disease
- Medicines to treat diabetes
- Medicines used to suppress the immune system such as ciclosporin
- Antiarrhythmic 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
- Some antibiotics used for bacterial infections (such as moxifloxacin, azithromycin, clarithromycin,

erythromycin, roxithromycin). Taking these antibiotics at the same time as hydroxychloroquine may increase the chance of you getting side effects that affect your heart which could be life-threatening.

- 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
- Rifampicin (antibiotics)
- Grapefruit juice
- Anticoagulant drugs such as dabigatran and clopidogrel
- Medicines to treat high cholesterol, such as gemfibrozil, statins
- Ritonavir (a medicine used to treat HIV)

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

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Plaquenil.

4. How do I use Plaquenil?

How much to take

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 or your child.

Plaquenil 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.

When to take Plaquenil

- Swallow tablets whole with a little water or other liquid.
- It is best to take Plaquenil at meal times.
- The dosage will depend on why you are being treated with Plaquenil.

If you forget to take Plaquenil

If you are being given Plaquenil 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 Plaquenil 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 it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

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

If you take too much Plaquenil

If you think that you have taken too much Plaquenil, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre in Australia **by calling 13 11 26**, or **0800 POISON** or **0800 764766** in New Zealand, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you take too many tablets you may experience headaches, drowsiness, visual disturbances or fits.

These symptoms may occur within 30 minutes of overdose.

5. What should I know while using Plaquenil?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Plaquenil.

Call your doctor straight away if you:

- Are about to start taking any new medicines, tell your doctor and pharmacist that you are taking Plaquenil.
- 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 recognise the symptoms of hypoglycaemia and know how to treat them.
- Your doctor will need to perform the following tests during treatment with Plaquenil:

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, Plaquenil 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 Plaquenil.

Serious skin reactions

- Serious skin reactions have been reported with the use of Plaquenil.
- Frequently, the rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes are often preceded by flu-like symptoms such as fever, headache and body ache. The rash may progress to widespread blistering and peeling of the skin.

- If you develop these skin symptoms, stop taking hydroxychloroquine and contact your doctor immediately.

Mental health problems

- Some people being treated with Plaquenil can experience mental health problems such as irrational thoughts, anxiety, hallucinations, feeling confused or feeling depressed, including thoughts of self-harm or suicide, even those who have never had similar problems before. If you or others around you notice any of these side effects (see section Side effects) seek medical advice straight away, and stop your treatment if you have thoughts of self-harm or suicide.

Talk to your doctor if you have a rare illness called porphyria which affects your metabolism.

Muscle and Nerve disorders

Hydroxychloroquine may cause muscle and nerve disorders. Caution should be taken when you take this medicine for a long time, your doctor will occasionally check for muscle weakness, numbness and pain.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Plaquenil affects you.

Plaquenil may cause dizziness in some people.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your tablets in the bottle until it is time to take them.
- If you take the tablets out of the bottle they will not keep well.
- Keep it in a cool dry place where the temperature stays below 25°C.
- Heat and dampness can destroy some medicines. Do not leave Plaquenil in the car on hot days.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Children are particularly sensitive to the unwanted effects of Plaquenil.

When to discard your medicine

If your doctor tells you to stop taking the tablets, ask your pharmacist what to do with any tablets that are left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Plaquenil 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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| <p>Stomach problems such as:</p> <ul style="list-style-type: none">• Nausea• Vomiting• Diarrhoea• Abdominal cramps <p>Other problems such as:</p> <ul style="list-style-type: none">• Loss of appetite• Muscle weakness• Dizziness• Ringing in the ears• Headache• Nervousness• Skin rash and itching• Hair loss <p>If you already have psoriasis, you are more likely to experience skin reactions than other people when taking Plaquenil.</p> | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|--|---|
| <ul style="list-style-type: none"> • 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. Symptoms may include a general feeling of being unwell, with or without jaundice (yellowing of the skin | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>Serious side effects are rare.</p> |

| Serious side effects | What to do |
|--|-------------------|
| <p>and eyes), dark urine, nausea, vomiting and/or abdominal pain.</p> <ul style="list-style-type: none"> ● Rare cases of liver failure (including fatal cases) have been observed. ● Kidney problems due to accumulation of phospholipids ● More severe symptoms of hypoglycaemia, including: <ul style="list-style-type: none"> ○ disorientation ○ seizures, fits or convulsions ○ loss of consciousness ● Rash with a fever and flu-like 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 | |

| Serious side effects | What to do |
|--|-------------------|
| <p>fever. This could be a condition called Acute Generalized Exanthematous Pustulosis (AGEP).</p> <ul style="list-style-type: none"> ● Blistering or peeling of the skin around the lips, eyes, mouth, nose, genitals, hands or feet, flu-like 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 | |

| Serious side effects | What to do |
|------------------------------------|-------------------|
| condition called Sweet's syndrome. | |

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects as follows:

Australia: Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems

New Zealand: Medsafe online at: <https://www.medsafe.govt.nz/safety/report-a-problem.asp>

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Plaquenil contains

| | |
|---|---|
| Active ingredient (main ingredient) | hydroxychloroquine sulfate |
| Other ingredients (inactive ingredients) | Calcium Hydrogen Phosphate Dihydrate Maize starch Magnesium Stearate Hypromellose Macrogol 400 Titanium dioxide Polysorbate 80 Carnauba Wax |
| Potential allergens | Not Applicable |

Do not take this medicine if you are allergic to any of these ingredients.

What Plaquenil looks like

Plaquenil comes as white to off-white peanut shaped tablets. A bottle contains 100 tablets.

In Australia: ARTG ID: 50055

Who distributes Plaquenil

Plaquenil is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Tel: 1800 818 806

Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

Freecall: 0800 283 684

Email: medinfo.australia@sanofi.com

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