

PLAQUENIL® TABLET

Hydroxychloroquine Sulphate (200mg)

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What Plaquenil is used for

Plaquenil can be used for:

- Rheumatoid arthritis (inflammation of the joints)
- Juvenile chronic arthritis (in children)
- Discoid and systemic lupus erythematosus (a disease of the skin or the internal organs)
- Skin problems which are due to/ aggravated by sunlight.

How Plaquenil works

Plaquenil contains a medicine called hydroxychloroquine sulphate.

It works by reducing inflammation in people with autoimmune diseases (this is where the body's immune system attacks itself by mistake).

Before you use Plaquenil

- When you must not use it

Do not take Plaquenil if:

- You are allergic (hypersensitive) any of the other ingredients of 4-aminoquinoline compounds (listed in section 8 below)
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have an eye problem which affects the retina, the inside of the eye (maculopathy) or you get a change in eye colour or any other eye problem
- Plaquenil 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.
- Plaquenil should not be used during breast-feeding unless your doctor considers the benefits outweigh the risks.

Do not use this medicine if any of the above apply to you. If you are not sure,

talk to your doctor or pharmacist before taking Plaquenil.

- Before you start to use it

Take special care and check with your doctor 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.
- You have liver or kidney problems
- You have serious stomach or gut problems
- You are taking a drug called Tamoxifen, used to treat breast cancer
- You have any problems with your blood. You may have blood tests to check this
- You have heart problems (signs include breathlessness and chest pain) which may require monitoring
- You have any problems with your nervous system or brain
- You have psoriasis (red scaly patches on the skin usually affecting the knees, elbows and scalp)
- You have had a bad reaction to quinine in the past
- You have a genetic condition known as 'glucose-6-dehydrogenase deficiency'
- You have a rare illness called 'porphyria' which affects your metabolism
- You have an inactive chronic infection with hepatitis B virus, varicella zoster virus (chickenpox/shingles) or tuberculosis
- Hydroxychloroquine can cause lowering of the blood glucose level. Please ask your doctor to inform you of signs and symptoms of low blood glucose levels. A check of the blood glucose level may be necessary
- Hydroxychloroquine may cause heart rhythm disorders in some patients: caution should be taken when using hydroxychloroquine if you were born with or have family history of prolonged QT interval, if you have acquired QT prolongation (seen on ECG, electrical recording of the heart), if you have heart disorders or have a history of heart attack (myocardial

infarction), if you have salt imbalance in the blood (especially low level of potassium or magnesium, see section "Taking other medicines"). If you experience palpitations or irregular heart beat, you should inform your doctor immediately. The risk of heart problems may increase with increase of the dose. Therefore, the recommended dosage should be followed.

- Serious skin rashes have been reported with the use of hydroxychloroquine. 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.

- 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.

- 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 seek medical advice straight away.

- You have lactose intolerance.

Before treatment with Plaquenil:

- Before you take Plaquenil you should have your eyes examined. This testing should be repeated at least every 12 months whilst taking Plaquenil.
- If you are over 65, need to take a high dose (2 tablets a day) or have kidney problems, then this examination should be performed more often.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Plaquenil.

- Taking other medicines

Tell your doctor, if you are taking the following medicines which may increase the chance of you getting side effects:

- Some antibiotics used for infections
- Cimetidine - used for stomach ulcers
- Neostigmine and pyridostigmine – used for muscle weakness (myasthenia gravis)
- Medicines that may affect the kidney or liver
- Medicines that affect the skin or the eyes
- Medicines known to affect the rhythm of your heart. This includes medicines used for abnormal heart rhythm (antiarrhythmics), for depression (tricyclic antidepressants), for psychiatric disorders (antipsychotics), for bacterial infections (e.g., moxifloxacin, macrolides including azithromycin, roxithromycin, spiramycin), or against malaria (e.g., halofantrine).
- Medicines for lipid disorders (such as gemfibrozil, statins)
- Medicines for depression (fluoxetine, paroxetine)

The following medicines can change the way Plaquenil works or Plaquenil may affect the way some of these medicines work:

- Digoxin - used for heart problems
- Medicines for epilepsy
- Medicines for diabetes (such as insulin/ oral antidiabetic drugs)
- Antacids - used for heartburn or indigestion. You should leave a gap of at least 2 hours between taking these medicines and Plaquenil.
- Rabies vaccine
- Praziquantel
- Ciclosporin
- Agalsidase
- Itraconazole
- clarithromycin
- rifampicin
- ritonavir
- grapefruit juice

How to use Plaquenil

Always take Plaquenil exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Swallow the tablets orally.
- Take this medicine with a meal or a glass of milk.

- How much to use

Adults (including the elderly)

- One or two tablets each day

- The dose can be reduced from 400mg daily to 200mg when there is no further improvement.

Children

- One tablet each day
- This medicine is only suitable for children whose ideal body weight is more than 31kg.

It may take several weeks before you notice the benefit of taking Plaquenil, however, side effects may occur relatively early.

- When to use it

Take Plaquenil at about the same time each day unless your doctor tells you otherwise.

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

If you are not sure when to use it, ask your doctor or pharmacist.

- How long to use it

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

- If you forget to use it

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten tablet.

- If you stop using it

Keep taking Plaquenil until your doctor tells you to stop. Do not stop taking Plaquenil just because you feel better. If you stop, your illness may get worse again.

- If you use too much (overdose)

If you take more Plaquenil than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. The following effects may happen: headache, problems with your eyesight, low potassium, fall in blood pressure, convulsions (fits), heart problems, leading to uneven heart beats, followed by sudden severe breathing problems and possibly heart attack. Overdose of Plaquenil may have a fatal outcome. Young children and babies are particularly at risk if they accidentally take Plaquenil. Take the child to a hospital straight away.

While you are using it

- Things you must do

Tell your doctor immediately and

- Stop taking Plaquenil if you are pregnant, might become pregnant or think you may be pregnant
- Stop taking Plaquenil if you are breast-feeding or planning to breast-feed

- Stop taking Plaquenil immediately if any disturbances of vision (including abnormal colour vision).

- Things you must not do

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Plaquenil or change the dosage, without checking with your doctor.
- Avoid taking grapefruit juice as it may increase the risk of side effects.

- Things to be careful of

Driving and using machines

You may get eye problems while taking this medicine. If you experience these side effects, do not drive or use any tools or machines, and tell your doctor straight away.

Blood Tests:

-Periodic blood counts are advised for patients on long-term therapy and Plaquenil should be discontinued if abnormalities occur.

-A blood test may show changes in the way the liver is working and occasionally the liver may stop working.

Side Effect

All medicines can cause side effects although not everybody gets them. Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Stop taking Plaquenil and see a doctor straight away if you notice any of the following serious side effects:

-Eye problems:

- This includes changes in the colour of your eye and problems with your eyesight such as blurring, sensitivity to light or the way you see colour

-Skin effects:

- 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 fever. This could be a condition called Acute Generalized Exanthematous Pustulosis (AGEP).

- Blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This known as 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 plum-coloured, 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.

- Severe red scaly rash, skin bumps that contain pus, blisters or peeling of skin, which may be associated with a high fever and joint pain. This could be a condition called Erythema multiforme

- sunburn-like reactions (following exposure to light)
- Skin rashes, itching, changes in the colour of your skin or the inside of your nose or mouth
- Psoriasis (red scaly patches on the skin usually affecting the knees, elbows and scalp)
- Hair loss or loss of hair colour
- You have an allergic reaction. The signs may include: a red or lumpy rash, swallowing or breathing problems, swelling of your eyelids, lips, face, throat or tongue.

-Stomach and intestinal problems:

- Diarrhoea, nausea, loss of appetite (anorexia) or stomach pain

-Brain problems:

- Feeling nervous, ringing in the ear (tinnitus), hearing loss, headache, fits, balance problems (vertigo) or feeling dizzy

- Feeling depressed, feeling nervous or anxious, feeling confused, agitated, difficulty sleeping, delusions, hallucinations, changes in mood, feeling elated or overexcited. Not known (frequency cannot be estimated from the available data)

-Muscle problems:

- You have any muscle weakness, cramps, stiffness or spasms or changes in sensation such as tingling
- Trembling, muscle spasm or irregular jerky movements

-Blood problems:

- You have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leucopenia' or 'agranulocytosis'.

- You may get infections more easily than usual. This could be due to bone marrow depression or a blood disorder called 'agranulocytosis'

- You may bruise more easily than usual. This could be due to a blood problem called 'thrombocytopenia'
- You feel tired, faint or dizzy and have pale skin. These could be 'anaemia'
- You feel weak, short of breath, bruise more easily than usual and get infections more easily than usual. These could be 'aplastic anaemia'

-Heart problems:

- Weakening of the heart muscle (cardiomyopathy) resulting in difficulty in breathing, coughing, high blood pressure, swelling, increased heart rate, low amount of urine
- Abnormal heart rhythm, life-threatening irregular heart rhythm (seen on ECG)

-Liver problems:

- 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.

-Others:

- Having thoughts of self-harm or suicide (see *Before you start to use it*)

- Symptoms of a condition called 'porphyria' which may include stomach pain, being sick, fits, blisters, itching

- Symptoms of lowering of the blood glucose level (hypoglycaemia). You may feel a sense of nervousness, shaky or sweaty

- If you take this medicine for a long time, your doctor will occasionally check your muscles and tendons to make sure they are working properly

- Accumulation of a type of fat in tissues causing harm. The doctor may decide to stop the treatment with Plaquenil.

Talk to your doctor or pharmacist if you get any of the side effects or if you notice any side effects not listed in this leaflet.

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

Storage and Disposal of Plaquenil

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

- Storage

- Keep this medicine in a safe place where children cannot see or reach it.
- Do not use Plaquenil after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store in a cool place below 30°C.

- 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

Plaquenil 200mg Film-coated Tablets are white, biconvex film coated tablets with "HCQ" on one side and "200" on the other. They are supplied in boxes of 60 tablets.

- Ingredients:

Active ingredient:
200mg hydroxychloroquine Sulphate

Inactive ingredients:

Lactose monohydrate, maize starch, magnesium stearate, povidone, Opadry OY-L-28900 (containing macrogol 4000, hypromellose, titanium dioxide (E171), lactose monohydrate).

- MAL Numbers:

MAL04103442AZ

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