

Package leaflet: Information for the user

Plaquenil 200mg Film-coated Tablets hydroxychloroquine sulphate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Plaquenil is and what it is used for
2. What you need to know before you take Plaquenil
3. How to take Plaquenil
4. Possible side effects
5. How to store Plaquenil
6. Further information

1. What Plaquenil is and what it is used for

Plaquenil contains a medicine called hydroxy-chloroquine sulphate.

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

It can be used for:

- Rheumatoid arthritis (inflammation of the joints)
- Juvenile idiopathic arthritis (inflammation of the joints)
- Discoid and systemic lupus erythematosus (a disease of the skin or internal organs)
- Skin problems which are sensitive to sunlight

2. What you need to know before you take Plaquenil

Do not take Plaquenil and tell your doctor if:

- You are allergic (hypersensitive) to:
 - hydroxychloroquine
 - other similar medicines such as quinolones and quinine
 - any of the other ingredients of Plaquenil (listed in Section 6 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 should not be used in children under 6 years of age or below 35kg.

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 Plaquenil.

Warnings and precautions

Talk to your doctor or pharmacist before taking Plaquenil 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 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), if you take medicines known to affect the rhythm of your heart (see section "Other medicines and hydroxychloroquine"). 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 (see section 4 possible side effects). 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 (see section 4) seek medical advice straight away.

Before treatment with Plaquenil

- Before you take this medicine 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 applies to you, talk to your doctor or pharmacist before taking Plaquenil.

Children

Plaquenil should not be used in children under 6 years of age or below 35kg. Small children are particularly sensitive to the toxic effect of quinolones, so Plaquenil should be kept out of the reach of children

Other medicines and Plaquenil

Please tell your doctor or pharmacist if you are taking, have recently taken or might use any other medicines, including medicines obtained without a prescription. This includes in particular:

- 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)
 - for HIV treatment (e.g., saquinavir)
 - for fungal infections (e.g., fluconazole)
 - for parasitic infections (e.g., pentamidine)
 - or against malaria (e.g., halofantrine).
- Insulin or other medicines for diabetes
- Medicines for malaria such as mefloquine (as it may increase the risk of seizures)
- Medicines for epilepsy (seizures), in particular phenobarbital, phenytoin, carbamazepine
- Medicines that affect the skin, the blood or the eyes
- Tamoxifen, used to treat breast cancer
- Agalsidase (used for a rare disease named “Fabry disease”)
- Medicines for bacterial infections (such as rifampicin, clarithromycin, and those named “aminosides” such as gentamicin, neomycin or tobramycin)
- Neostigmine and pyridostigmine - used for muscle weakness (myasthenia gravis)
- Rabies vaccine
- Medicines that may affect the kidney or liver
- Antacid medicines (for heartburn) and kaolin: Take Plaquenil at least 2 hours apart from those.
- Cimetidine (used for stomach ulcers)
- Medicines for fungal infections (such as itraconazole)
- Medicines for lipid disorders (such as gemfibrozil, statins)
- Medicines for HIV treatment (such as ritonavir)
- Medicines for organ transplantation or immune system disorders (such as ciclosporin)
- Medicines for blood clots (such as dabigatran, clopidogrel)
- Medicines for heart diseases (such as digoxin, flecainide, propafenone, quinidine and metoprolol)
- Praziquantel (an antiparasitic medicine)
- Medicines for depression (fluoxetine, paroxetine)
- an herbal treatment for depression: St. John’s wort.

Plaquenil with food and drink

Avoid taking grapefruit juice as it may increase the risk of side effects.

Pregnancy and breast-feeding

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.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding. Your doctor will discuss with you whether Plaquenil is suitable for you.

Driving and using machines

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

Important information about some of the ingredients of Plaquenil

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Plaquenil.

3. How to take Plaquenil

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

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with a meal or a glass of milk. Do not crush or chew your tablets
- If you are taking this medicine for skin problems that are sensitive to sunlight, only take Plaquenil during periods of high exposure to light
- The doctor will work out the dose depending on your body weight. If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor
- If you have been taking this medicine for rheumatoid arthritis for a long time (more than 6 months) and you do not feel that it is helping you, see your doctor. This is because the treatment may need to be stopped.

How much to take

Adults including the elderly

- One or two tablets each day

Children and adolescents

- One tablet each day
- This medicine is only suitable for children who weigh more than 35kg (around 5.5 stone)

It may take several weeks before you notice the benefit of taking Plaquenil.

If you take more Plaquenil than you should

- If you take more Plaquenil than you should, tell a doctor or go to a hospital casualty department **straight away**. Take the medicine with you.
- This is so the doctor knows what you have taken. The following effects may happen: headache, problems with your eyesight, 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

If you forget to take Plaquenil

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 dose.

If you stop taking Plaquenil

Keep taking your medicine 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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Plaquenil and see a doctor or go to a hospital straight away if:

Not known (frequency cannot be estimated from available data):

- 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.

Stop taking Plaquenil and see a doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

Common side effects (may affect less than 1 in 10 people):

- You have any eye problems. This includes problems with your eyesight such as blurring

Uncommon side effects (may affect less than 1 in 100 people):

- You have any eye problems such as sensitivity to light or the way you see and the change in the colour of your eye
- You have any muscle weakness, cramps, stiffness or spasms or changes in sensation such as tingling which can lead to difficulty in moving

Not known (frequency cannot be estimated from available data):

- Severe skin reactions (see section 2 Warnings and precautions) such as
 - 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 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 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)
- Having thoughts of self-harm or suicide (see section 2 Warnings and precautions).
 - You have an eye problem which affects the retina, the inside of the eye (maculopathy)
 - 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 symptoms of something called ‘anaemia’
 - You feel weak, short of breath, bruise more easily than usual and get infections more easily than usual. These could be symptoms of something called ‘aplastic anaemia’
 - 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.
 - Abnormal heart rhythm, life-threatening irregular heart rhythm (seen on ECG) (see section Warnings and precautions)
 - 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

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

Very common side effects (may affect more than 1 in 10 people):

- Stomach pain
- Feeling or being sick

Common side effects (may affect up to 1 in 10 people):

- Skin rashes, itching
- Vomiting, diarrhoea
- Loss of appetite (anorexia)
- Headache
- Changes in mood

Uncommon side effects (may affect up to 1 in 100 people):

- Changes in the colour of your skin or the inside of your nose or mouth
- Hair loss or loss of hair colour
- Feeling nervous
- Ringing in the ear (tinnitus)
- Balance problems (vertigo) or feeling dizzy
- Liver problems shown by blood tests

Not known (frequency cannot be estimated from the available data):

- Psoriasis (red scaly patches on the skin usually affecting the knees, elbows and scalp)

- Feeling depressed, feeling nervous or anxious, feeling confused, agitated, difficulty sleeping, delusions, hallucinations, feeling elated or overexcited (see section 2 Warnings and Precautions).
- Hearing loss
- Weakening of the heart muscle (cardiomyopathy) resulting in difficulty in breathing, coughing, high blood pressure, swelling, increased heart rate, low amount of urine
- 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
- Trembling, muscle spasm or irregular jerky movements
- Accumulation of a type of fat in tissues causing harm. (see section 2 Warnings and Precautions). The doctor may decide to stop the treatment with Plaquenil.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance; Website: www.hpra.ie

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

5. How to store Plaquenil

Keep this medicine out of the sight and reach of children. This medicine does not require any special storage conditions.

Do not use Plaquenil after the expiry date which is stated on the carton and blister foil after EXP. The expiry date refers to the last day of that month.

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.

6. Further Information

What Plaquenil contains

- Each tablet contains 200mg of the active substance, hydroxychloroquine sulphate
- The other ingredients are lactose monohydrate, maize starch, magnesium stearate, povidone, hypromellose, macrogol 4000, and titanium dioxide (E171)

What Plaquenil looks like and contents of the pack

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

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
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This medicinal product is authorised in the Member States of the EEA under the following names:
Ireland, Hungary: Plaquenil

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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