

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 hydroxychloroquine 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 (in children)
- Discoid and systemic lupus erythematosus (a disease of the skin or the internal organs)
- Skin problems which are sensitive to sunlight

2. What you need to know before you take Plaquenil

Do not take Plaquenil 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
- You are pregnant, might become pregnant or think you may be pregnant (see 'Pregnancy and breast-feeding' below)
- 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 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
- 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.

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. This includes medicines you buy without a prescription, including herbal medicines. This is because Plaquenil can affect the way some other medicines work.

Also some medicines can affect the way Plaquenil works.

In particular, tell your doctor if you are taking any of the following:

The following medicines may increase the chance of you getting side effects when taken with Plaquenil:

- Some antibiotics used for infections (such as gentamicin, neomycin or tobramycin)
- 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 used to treat malaria (such as halofantane, mefloquine, moxifloxacin)
- Some medicines used to treat arrhythmias (amiodarone)

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 or metformin)
- Antacids - used for heartburn or indigestion. You should leave a gap of at least 4 hours between taking these medicines and Plaquenil
- Rabies vaccine
- Praziquantel
- Ciclosporin
- Agalsidase

Pregnancy and breast-feeding

Do not take Plaquenil if:

- You are pregnant, might become pregnant or think you may be pregnant
 - You are breast-feeding or planning to breast-feed. This is because small amounts may pass into mothers' milk
- Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

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 can not tolerate some sugars, talk to your doctor before taking Plaquenil.

3. How to take Plaquenil

Always take Plaquenil exactly as your doctor has told you. 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 pack 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, 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 tablet.

If you stop taking Plaquenil

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 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:

- 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:

- A small number of people being treated with Plaquenil have had thoughts of harming or killing themselves. If at any time you have had these thoughts, immediately contact your doctor
 - You have any 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
 - You have any muscle weakness, cramps, stiffness or spasms or changes in sensation such as tingling
- 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
- Severe skin reactions such as blistering, widespread scaly skin, pus-filled spots together with a high temperature
 - 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
- Multiple skin lesions, itching of the skin, joint aches, fever and a general ill feeling. This could be a condition called Toxic Epidermal Necrolysis.
 - 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 that may cause the eyes or skin to go yellow (jaundice)

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

- 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
- Feeling or being sick, diarrhoea, loss of appetite (anorexia) or stomach pain
- Feeling nervous, ringing in the ear (tinnitus), hearing loss, headache, fits, balance problems (vertigo) or feeling dizzy, mental problems (such as delusions, hallucinations or changes in mood)
- Weakening of the heart muscle (cardiomyopathy) resulting in difficulty in breathing, coughing, high blood pressure, swelling, increased heart rate, low amount of urine
- You may get infections more easily than usual. This could be due to bone marrow depression
- 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.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine. Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST
 Pharmacovigilance Section
 Irish Medicines Board
 Kevin O'Malley House
 Earlsfort Centre
 Earlsfort Terrace
 Dublin 2
 Tel: +353 1 6764971
 Fax: +353 1 6762517
 Website: www.imb.ie
 e-mail: imbpharmacovigilance@imb.ie

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

5. How to store Plaquenil

Keep out of the reach and sight of children. Do not store above 25°C. 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 Tablets are round white film coated tablets with HCQ on one side and 200 on the other. They are supplied in over-labelled outer cartons containing 60 tablets.

Product procured from within the EU by the Parallel Product Authorisation Holder:

IMED Healthcare Ltd, New Road, Buncrana, Co. Donegal, Ireland.

Manufacturer:

Fawdon Manufacturing Centre,
 Edgefield Avenue, Fawdon,
 Newcastle-upon-Tyne,
 Tyne & Wear, NE3 3TT, UK.

Repackager:

Cast Healthcare Ltd, Unit B6 The Business Centre, 5-7 Tobermore Road, Draperstown, Northern Ireland, BT45 7AG, UK

Date of last revision: December 2013

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1. What Plaquenil is and what it is used for

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It can be used for:

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- Juvenile idiopathic arthritis (in children)
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- Skin problems which are sensitive to sunlight

2. What you need to know before you take Plaquenil

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- 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
- You are pregnant, might become pregnant or think you may be pregnant (see 'Pregnancy and breast-feeding' below)
- 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:

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- 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
- 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.

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

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Children

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- Medicines that affect the skin or the eyes
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- Medicines for epilepsy
- Medicines for diabetes (such as insulin or metformin)
- Antacids - used for heartburn or indigestion. You should leave a gap of at least 4 hours between taking these medicines and Plaquenil
- Rabies vaccine
- Praziquantel
- Ciclosporin
- Agalsidase

Pregnancy and breast-feeding

Do not take Plaquenil if:

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- Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

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 can not tolerate some sugars, talk to your doctor before taking Plaquenil.

3. How to take Plaquenil

Always take Plaquenil exactly as your doctor has told you. 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 pack 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, 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 tablet.

If you stop taking Plaquenil

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

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- Severe skin reactions such as blistering, widespread scaly skin, pus-filled spots together with a high temperature
 - 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
- Multiple skin lesions, itching of the skin, joint aches, fever and a general ill feeling. This could be a condition called Toxic Epidermal Necrolysis.
 - 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 that may cause the eyes or skin to go yellow (jaundice)

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

- 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
- Feeling or being sick, diarrhoea, loss of appetite (anorexia) or stomach pain
- Feeling nervous, ringing in the ear (tinnitus), hearing loss, headache, fits, balance problems (vertigo) or feeling dizzy, mental problems (such as delusions, hallucinations or changes in mood)
- Weakening of the heart muscle (cardiomyopathy) resulting in difficulty in breathing, coughing, high blood pressure, swelling, increased heart rate, low amount of urine
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- Symptoms of a condition called 'porphyria' which may include stomach pain, being sick, fits, blisters, itching
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Blood Tests

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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine. Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST
 Pharmacovigilance Section
 Irish Medicines Board
 Kevin O'Malley House
 Earlsfort Centre
 Earlsfort Terrace
 Dublin 2
 Tel: +353 1 6764971
 Fax: +353 1 6762517
 Website: www.imb.ie
 e-mail: imbpharmacovigilance@imb.ie

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

5. How to store Plaquenil

Keep out of the reach and sight of children. Do not store above 25°C. 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

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Authorisation Holder:

IMED Healthcare Ltd, New Road, Buncrana, Co. Donegal, Ireland.

Manufacturer:

Fawdon Manufacturing Centre,
 Edgefield Avenue, Fawdon,
 Newcastle-upon-Tyne,
 Tyne & Wear, NE3 3TT, UK.

Repackager:

Cross Healthcare Ltd, Unit 2A Bandeath Industrial Estate, Throsk, Stirlingshire, FK7 7NP, UK

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