5. How to store Plaquenil

Keep out of the reach and sight of children. Store below 25°C.

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.

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, polyvinylpyrrolidone, hypromellose, macrogol 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 HQC on one side and 200 on the other. They are supplied in boxes of 60 tablets.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YJ, UK
Tel: 0845 272 7181
email: uk-medicalinformation@sanofi.com
Manufacturer Fawdon Manufacturing Centre, Edgefield Avenue, Fawdon, Newcastle-upon-Tyne, Tyne & Wear, NE3 3TT, UK

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.

This leaflet was last revised in 2011
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2. Before you take Plaquenil

Do not take this medicine 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)
• You have or had porphyria which may include stomach pain, being sick, fits, blisters, itching
• 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

Is this leaflet hard to see or read?
Phone 0845 372 7101 for help
Read all of this leaflet carefully before you start taking this medicine
• 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Plaquenil is and what it is used for
2. 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

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• If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
Before you take this medicine you should check with your doctor or pharmacist if you are not sure.

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 cannot 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.

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 any allergy 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:
• 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 your eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition called Stevens-Johnson syndrome
• 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 bone marrow depression or a blood disorder called 'agranulocytosis'
• You may feel weak, short of breath, bruise or skin to go yellow (jaundice)
• 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.

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
• Hydroxychloroquine can cause lowering of the blood glucose level.

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 31kg (around 5 stones). 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.

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.

Taking this medicine
• You may get infections more easily that 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
The following medicines may change the way Plaquenil works or Plaquenil may affect the way some of these medicines work:
• Diclofen - used for heart problems
• 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
• Babies vaccine
• Pregnant and breast-feeding
• 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
• Hydroxychloroquine can cause lowering of the blood glucose level.

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

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken 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:
• 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
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Rabies vaccine

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Important information about some of the ingredients of Plaquenil
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How much to take
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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.

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.

Young children and babies are particularly at risk if they accidentally take Plaquenil. Take the child to a hospital straight away.

How much to take
Adults, including the elderly

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’.

If you stop taking Plaquenil
If you stop taking Plaquenil, your illness may get worse again.

Driving and using machines
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5. How to store Plaquenil

Keep out of the reach and sight of children. Store below 25°C. 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.

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6. Further information

What Plaquenil contains

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- The other ingredients are lactose monohydrate, maize starch, magnesium stearate, polypovidone, hypromellose, macrogol and titanium dioxide (E171).

What Plaquenil looks like and contents of the pack

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Marketing Authorisation Holder and Manufacturer

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- 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)

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.

Take special care with Plaquenil Check with your doctor or pharmacist before taking your medicine if:

- You have liver or kidney problems
- You have serious stomach or gut problems
- 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 a rare illness called 'porphyria' which affects your metabolism
- 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 genetic condition that affects the skin usually affecting the knees, elbows and scalp

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

- Skin rash, itching, changes in the colour of your skin or the inside of your nose or mouth
- Psoiasis (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

Blood Tests

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.

United Kingdom

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Malta

ADRA Reporting, The Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D’Argens, GZR-1368 Gżira
Website: www.medicinesauthority.gov.mt

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