

Hydroxychloroquine Sulfate
200mg Film-coated Tablets
Leaflet

Front

15 mm

8 mm

Package Leaflet: Information for user

Hydroxychloroquine Sulfate
200 mg film-coated Tablets

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 Hydroxychloroquine sulfate is and what it is used for
2. What you need to know before you take Hydroxychloroquine sulfate
3. How to take Hydroxychloroquine sulfate
4. Possible side effects
5. How to store Hydroxychloroquine sulfate
6. Contents of the pack and other information

1. What Hydroxychloroquine sulfate is and what it is used for

Hydroxychloroquine sulfate contains an active substance called hydroxychloroquine sulfate. Hydroxychloroquine sulfate 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 Hydroxychloroquine sulfate

Do not take Hydroxychloroquine sulfate and tell your doctor if:

- You are allergic (hypersensitive) to
 - o Hydroxychloroquine
 - o Other similar medicines such as quinolones and quinine
 - o Any of the other ingredients of Hydroxychloroquine sulfate (listed in Section 6).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 Hydroxychloroquine sulfate.

Some people being treated with Hydroxychloroquine sulfate 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.

Warnings and precautions

- Talk to your doctor or pharmacist before taking Hydroxychloroquine sulfate if:
- You have liver or kidney problems;
- You have serious stomach or gut problems;
- You have heart problems;
- You have any problems with your blood. You may have blood tests to check this.
- 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.

Before treatment with Hydroxychloroquine sulfate:

- Before you take this medicine you should have your eyes examined.
- This testing should be repeated at least every 12 months whilst taking Hydroxychloroquine sulfate.
- 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. 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.

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

Children and adolescents

This medicine is not suitable for children and adolescents who weigh less than 31 kg (around 5 stones).

Other medicines and Hydroxychloroquine sulfate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you can buy without a prescription, including herbal medicines. This is because Hydroxychloroquine sulfate can affect the way some other medicines work. Also some medicines can affect the way Hydroxychloroquine sulfate works.

Some antibiotics used for infections (such as azithromycin, clarithromycin, erythromycin, gentamicin, neomycin or tobramycin). Taking azithromycin, clarithromycin, or erythromycin at the same time as hydroxychloroquine may increase the chance of you getting side effects that affect your heart.

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 Hydroxychloroquine sulfate

- Some antibiotics used for infections (such as azithromycin, clarithromycin, erythromycin, 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
- Halofantrine, mefloquine – used for malaria
- Amiodarone – used for heart problems
- Moxifloxacin – used to treat infections
- Medicines used for epilepsy

The following medicines can change the way Hydroxychloroquine sulfate works or Hydroxychloroquine sulfate may affect the way some of these

medicines work:

- Digoxin – 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 hydroxychloroquine sulfate
- Rabies vaccine
- Ciclosporin – used after an organ transplantation to help prevent rejection
- Praziquantel – used to treat worm infections
- Agalsidase – used to treat a rare condition called Fabry's disease

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Hydroxychloroquine sulfate 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

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.

3. How to take Hydroxychloroquine sulfate

Always take this medicine exactly as your doctor has told you. 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 Hydroxychloroquine sulfate 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.

Front

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Hydroxychloroquine Sulfate
200mg Film-coated Tablets
Leaflet

Back

The recommended dose for adults, including the elderly, is:

- One or two tablets each day

Use in children and adolescents

- One tablet each day
- This medicine is only suitable for children who weigh more than 31 kg (around 5 stones)

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

If you take more Hydroxychloroquine sulfate than you should

Tell your 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 hydroxychloroquine sulfate. Take the child to hospital straight away.

If you forget to take Hydroxychloroquine sulfate

If you forget a dose, take it as soon as your 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 Hydroxychloroquine sulfate

Keep taking hydroxychloroquine sulfate until your doctor tells you to stop. Do not stop taking hydroxychloroquine sulfate 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

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

Frequency not known (the frequency cannot be established from the 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.

- Severe skin reactions such as blistering, widespread scaly skin, pus-filled spots together with a high temperature, reddening and being more sensitive to the sun.
- 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.
- Feeling depressed or having thoughts of self-harm or suicide, hallucinations, feeling nervous or anxious, feeling confused, agitated, difficulty sleeping, feeling elated or overexcited.

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

Common (may affect up to 1 in 10 people)

- 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.

Uncommon (may affect up to 1 in 100 people)

- 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.

Not known (the frequency cannot be established from the available data)

- You have frequent infections accompanied by fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leucopenia' or '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 and get infections more easily than usual. These could be symptoms of something called 'aplastic anaemia'.
- Weakening of the heart muscle (cardiomyopathy) resulting in difficulty breathing, coughing, high blood pressure, swelling, increased heart rate, low amount of urine.
- Low blood sugar levels (hypoglycaemia). You may feel a sense of nervousness, shaky or sweaty.
- You notice yellowing of your skin or eyes or if your urine becomes darker in colour. This could be a liver problem, such as jaundice or hepatitis.
- Fits.
- Lack of movement, stiffness, shaking or abnormal movements in the mouth and tongue.

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

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

- Stomach pain
- Feeling sick

Common (may affect up to 1 in 10 people)

- Skin rashes, itching
- Being sick, diarrhoea
- Loss of appetite (anorexia)
- Headache
- Changes in mood with uncontrollable laughing or crying

Uncommon (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

- Psoriasis (red scaly patches on the skin usually affecting the knees, elbows and scalp)
- Hearing loss
- Mental problems (such as delusions, hallucinations and changes in mood)
- Symptoms of a condition called 'porphyria' which may include stomach pain, being sick, fits, blisters, itching

Heart and blood tests

- Your doctor may look at your heart's electrical activity using an ECG (electrocardiogram) machine.
- 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can

help provide more information on the safety of this medicine.

5. How to store Hydroxychloroquine sulfate

Keep this medicine out of sight and reach of the children,

Store in original package in order to protect from light.

Do not use Hydroxychloroquine sulfate after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Hydroxychloroquine sulfate contains

- The active substance is hydroxychloroquine sulfate. Each film-coated tablet contains 200 mg of hydroxychloroquine sulfate.
- The other ingredients are: Maize starch, Calcium hydrogen phosphate dihydrate, Silica Colloidal Anhydrous, Polysorbate 80, Talc, Magnesium stearate, Hypromellose, Titanium dioxide, Macrogol 6000.

What Hydroxychloroquine sulfate looks like and contents of the pack

Hydroxychloroquine sulfate 200 mg film-coated tablets are white, approximately 9.5 mm circular, biconvex, film-coated tablets debossed with 200 on one side and plain on the other side. They are supplied in transparent PVC/Aluminium blister of 10 tablets. Pack size: 30 and 60 tablets.

Marketing Authorisation Holder and Batch Release Site



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