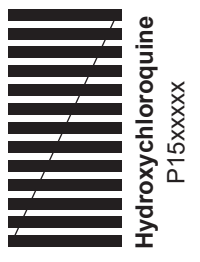
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Package Leaflet: Information for the user

Hydroxychloroquine sulfate 200 mg film-coated tablets

Hydroxychloroquine sulfate

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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Hydroxychloroquine sulfate film-coated tablets are and what it is used for

Hydroxychloroquine sulfate film-coated tablets contains an active substance called hydroxychloroquine sulfate.

Hydroxychloroquine sulfate film-coated tablets 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 film-coated tablets

Do not take Hydroxychloroquine sulfate film-coated tablets and tell your doctor if:
- are allergic (hypersensitive) to:
  - Hydroxychloroquine.
  - Other similar medicines such as quinolones and quinine
  - 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.
- 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.

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 film-coated tablets.

Warnings and precautions
Talk to your doctor or pharmacist before taking Hydroxychloroquine sulfate film-coated tablets if you:
- have liver or kidney problems.
- have serious stomach or gut problems.
- have heart problems.
- have any problems with your blood. You may have blood tests to check this.
- have any problems with your nervous system or brain.
- have psoriasis (red scaly patches on the skin usually affecting the knees, elbows and scalp).
- have had a bad reaction to quinine in the past.
- have a genetic condition known as 'glucose-6-dehydrogenase deficiency'.
- have a rare illness called 'porphyria' which affects your metabolism
- have an inactive chronic infection with hepatitis B virus
- are taking any medicines known to cause damage to the eyes (such as tamoxifen).
- were born with or have family history of prolonged QT interval or you have acquired QT prolongation (seen on ECG, electrical recording of the heart).
- have heart disorders or have a history of heart attack (myocardial infarction), as hydroxychloroquine may cause heart rhythm disorders in some patients
- 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.
- have salt imbalance in the blood (especially low level of potassium or magnesium, see section "Other medicines and hydroxychloroquine").

Serious skin rashes have been reported with the use of hydroxychloroquine film-coated tablets (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 film-coated tablets and contact your doctor immediately.

Before treatment with Hydroxychloroquine sulfate film-coated tablets:
- 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 film-coated tablets.
- 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 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.
- Some people being treated with hydroxychloroquine sulfate film-coated tablets 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.

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

Other medicines and Hydroxychloroquine sulfate film-coated tablets
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 hydroxychloroquine sulfate film-coated tablets can affect the way some other medicines work. Also some medicines can affect the way hydroxychloroquine sulfate film-coated tablets 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 hydroxychloroquine sulfate film-coated tablets
- 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.
- Cimetidine – used for stomach ulcers.
- Neostigmine and pyridostigmine – used for muscle weakness (myasthenia gravis).
- Medicines that may affect the kidneys or liver.
- Medicines that affect the skin.
- Medicines that affect the eyes (such as tamoxifen)
- Halofantrine, mefloquine – used for malaria.
- Medicines used for heart problems (such as amiodarone).
- Moxifloxacin – used to treat infections.
- Medicines used for epilepsy.
- Medicines used for psychiatric disorders (such as amisulpride, quetiapine, risperidone).

The following medicines can change the way hydroxychloroquine sulfate film-coated tablets works or hydroxychloroquine sulfate film-coated tablets 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 film-coated tablets.
- 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
Hydroxychloroquine sulfate film-coated tablets may be associated with a small increased risk of major malformations and should not be used during pregnancy unless your doctor considers the benefits outweigh the risks.

If you discover that you are pregnant or are planning to have a baby, consult your doctor right away to reassess the need for treatment. Hydroxychloroquine should not be used during breast-feeding unless your doctor considers the benefits outweigh the risks. This is because small amounts may pass into mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breastfeeding. Your doctor will discuss with you whether hydroxychloroquine 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.

Hydroxychloroquine sulfate film-coated tablets contains lactose
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 this medicine.

3. How to take Hydroxychloroquine sulfate film-coated tablets

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 film-coated tablets 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 31kg(around 5 stones)

It may take several weeks before you notice the benefit of taking hydroxychloroquine sulfate film-coated tablets.

If you take more Hydroxychloroquine sulfate film-coated tablets than you should
- If you take more hydroxychloroquine sulfate film-coated tablets 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 leading to uneven heart beats followed by sudden severe breathing problems and possibly heart attack.

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- Young children and babies are particularly at risk if they accidentally take hydroxychloroquine sulfate film-coated tablets. Take the child to a hospital straight away.

If you forget to take Hydroxychloroquine sulfate film-coated tablets 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 Hydroxychloroquine sulfate film-coated tablets

Keep taking hydroxychloroquine sulfate film-coated tablets until your doctor tells you to stop. Do not stop taking hydroxychloroquine sulfate film-coated tablets 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 film-coated tablets and see a doctor or go to a hospital straight away if:

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 the eyelids, lips, face, throat or tongue.

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

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.

Common (may affect less than 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 less than 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 (frequency cannot be estimated from available data)
- 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 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'.
- 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 your eyes or 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.
- Feeling depressed or having thoughts of self harm or suicide, hallucinations, feeling nervous or anxious, feeling confused, agitated, difficulty sleeping, feeling elated or overexcited.

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 sick.

Common **side effects (may affect less than 1 in 10 people)**
- Skin rashes, itching
- Being sick, diarrhoea
- Loss of appetite (anorexia)
- Headache
- Changes in mood with uncontrollable laughing or crying.

Uncommon side effects (may affect less than 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 available data)
- 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
- Chest pain and shortness of breath and irregular heartbeat (these could be signs of a condition called "Torsade de pointes"), or fast heartbeat (tachycardia)".

Tests
Your doctor may monitor:
- Your heart's electrical activity using an ECG(electrocardiogram) machine.
- Your muscle function and tendon reflexes.
- The levels of specific cells in your blood using occasional blood tests. A blood test may also 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 film-coated tablets

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

This medicinal product does not require any special storage conditions.

Do not use Hydroxychloroquine sulfate film-coated tablets 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 film-coated tablets contains
The active substance is hydroxychloroquine sulfate.
Each tablet contains 200 mg of hydroxychloroquine sulfate.

The other ingredients are:
Tablet Core:
Lactose monohydrate
Maize starch
Magnesium stearate

Tablet coat:
Hypromellose 2910 (5 mPas) (E464),
Titanium Dioxide (E171),
Macrogol 400 (E1521).

What Hydroxychloroquine sulfate film-coated tablets looks like and contents of the pack

Hydroxychloroquine sulfate 200 mg Film-Coated Tablets are film-coated tablet white, oval, biconvex, approximately 12.8 × 6mm film-coated tablets debossed with "HC" on one side and '200' on the other side are available in clear PVC-Aluminum foil blister.

Pack sizes:
Blister packs: 30, 60, 90 and 100 film-coated tablets.

Not all pack sizes may be marketed.

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