

PACKAGE LEAFLET: INFORMATION FOR THE USER

Hydroxychloroquine sulfate 200mg 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 possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Hydroxychloroquine sulfate Tablets are and what they are used for

Hydroxychloroquine sulfate tablets contain a medicine called hydroxychloroquine sulfate. Hydroxychloroquine sulfate tablets work 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 Tablets

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 this medicine (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 or breast-feeding (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.

Warnings and Precautions

Talk to your doctor or pharmacist before taking this medicine if:

- You have liver, kidney or heart 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 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

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of hydroxychloroquine, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.

- Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).
- These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin
- The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of hydroxychloroquine, you must not be re-started on this medicine at any time.

If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell him that you are taking this medicine.

Before treatment with Hydroxychloroquine sulfate 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
- 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

Other medicines and Hydroxychloroquine sulfate tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- 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 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 Hydroxy- chloroquine sulfate tablets work or Hydroxychloroquine sulfate 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 tablets
- Rabies vaccine
- Ciclosporin - used after an organ transplantation to help prevent rejection
- Praziquantel - used to treat worm infections
- Medicines known to have a toxic effect on the retina of your eyes (e.g. Tamoxifen)

Pregnancy, breast-feeding and fertility

Do not take Hydroxychloroquine sulfate if you are:

- pregnant, might become pregnant or think you may be pregnant.
- breast-feeding or planning to breast-feed. 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 breast-feeding.

Driving or 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 Tablets

Always take hydroxychloroquine sulfate exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults, including the elderly

- 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 31kg (around 5 stones). It may take several weeks before you notice the benefit of taking Hydroxychloroquine sulfate.

Route and method of administration

- Take this medicine by mouth.
- Swallow the tablets whole with a meal or a glass of milk. Do not crush or chew your tablets.

Duration of treatment

- If you are taking this medicine for skin problems that are sensitive to sunlight, only take Hydroxychloroquine sulfate 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.

If you take more Hydroxychloroquine sulfate Tablets than you should

- If you take more Hydroxychloroquine sulfate 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 these tablets. Take the child to a hospital straight away.

If you forget to take Hydroxychloroquine sulfate Tablets

- If you forget a dose, take it as soon as you remember. 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 Tablets

- 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 every-body gets them.

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

Not known (frequency cannot be estimated 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

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 (frequency cannot be estimated from the 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 in 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 and 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 (frequency cannot be estimated from the available data)

- Psoriasis (red scaly patches on the skin usually affecting the knees, elbows and scalp)
- Hearing loss
- Mental problems (such as delusions, hallucinations or 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 Tablets

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.
- Store in the original package.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Hydroxychloroquine sulfate Tablets contain

- The active substance is hydroxychloroquine sulfate. Each tablet contains 200mg hydroxychloroquine sulfate as the active ingredient.
- The other ingredients are- **Tablet core:** maize starch, calcium hydrogen phosphate dihydrate, colloidal anhydrous silica, polysorbate 80, purified talc, magnesium stearate. **Tablet coat:** Purified talc, hypromellose, titanium

dioxide and macrogol 6000.

What Hydroxychloroquine sulfate Tablets look like and content of the pack

- White, circular, biconvex, film coated tablets debossed with 'BL' on one side and '200' on the other.
- Hydroxychloroquine sulfate Tablets are supplied in blister packs of 30, 60 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Bristol Laboratories Ltd.,

Unit 3, Canalside, Northbridge Road, Berkhamsted, Hertfordshire, HP4 1EG, United Kingdom.

Telephone: 0044 (0) 1442 200922

Fax: 0044 (0) 1442 873717

Email: info@bristol-labs.co.uk

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