

PACKAGE LEAFLET: INFORMATION FOR THE USER

Hydroxychloroquine Sulfate 200 mg film-coated tablets

(referred to as Hydroxychloroquine Sulfate Tablets in the remainder of the leaflet)

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, please 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.

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

The name of your medicine is Hydroxychloroquine Sulfate Tablets; the active ingredient is hydroxychloroquine sulfate. These tablets are used in the treatment of inflammatory diseases such as rheumatoid arthritis and juvenile idiopathic arthritis. They are also used to treat discoid and systemic lupus erythematosus (a disease where the immune system attacks the body causing tissue damage and inflammation) and also in problems with the skin that are triggered or worsened by sunlight.

2. What you need to know before you take Hydroxychloroquine Sulfate Tablets

Do not take Hydroxychloroquine Sulfate Tablets if you:

- are allergic (hypersensitive) to hydroxychloroquine sulfate or to any of the other ingredients in Hydroxychloroquine Sulfate Tablets (listed in section 6, Contents of the pack and other information)
- are allergic (hypersensitive) to 4-aminoquinolone compounds (e.g. chloroquine, amodiaquine)
- suffer from maculopathy (a disease of the eye)

Before starting this medicine your doctor should arrange for you to have a thorough eye test.

- this should be repeated at least once every year while you are taking this medicine
- the elderly, those with kidney or previous eye problems and those taking more than one tablet per day may need more frequent eye tests.

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 before taking Hydroxychloroquine Sulfate Tablets if you:

- suffer from liver or kidney disease
- suffer from severe problems with your gastrointestinal system or nervous system
- suffer from heart problems
- suffer from severe problems with your blood or bone marrow
- suffer from porphyria (a disease of blood proteins that can affect the skin, gut and nervous system)
- have the inherited condition glucose-6-phosphate dehydrogenase (G6PD) deficiency (an enzyme deficiency which increases the risk of developing anaemia)
- suffer from psoriasis (a skin condition causing scaly skin patches over the body)
- have eye or eyesight problems
- are taking any medicines known to cause damage to the eyes (such as tamoxifen)
- are allergic to quinine (a medicine used to treat malaria).

Other medicines and Hydroxychloroquine Sulfate Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, tell your doctor if you are taking any of the following 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 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.
- medicines used to treat myasthenia gravis – a disease of the muscles and nerves (e.g. neostigmine and pyridostigmine)
- aminoglycoside antibiotics (used to treat bacterial infections)
- cimetidine (used to treat heartburn and stomach ulcers)
- medicines that affect the skin or the eyes (such as tamoxifen)
- medicines that may affect the kidney or liver.
- halofantrine, mefloquine (used to treat malaria)
- amiodarone (used to treat heart problems)
- moxifloxacin (used to treat infections)
- medicines used to treat epilepsy

The following medicines can change the way Hydroxychloroquine Sulfate Tablets work or Hydroxychloroquine Sulfate Tablets may affect the way some of these medicines work:

- medicines used to treat diabetes (e.g. insulin and antidiabetic tablets)
- digoxin (used to treat abnormal heart rhythms and heart failure)
- rabies vaccine
- antacids (medicines used to treat indigestion) – you should wait at least four hours between taking antacids and Hydroxychloroquine Sulfate Tablets.
- ciclosporin (used after organ transplant to help prevent rejection)
- praziquantel (used to treat worm infections)
- agalsidase (used to treat a rare condition called Fabry's disease)

Taking Hydroxychloroquine Sulfate Tablets with food and drink

Hydroxychloroquine Sulfate Tablets should be taken with a meal or a glass of milk.

Pregnancy and breast-feeding and fertility

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. Your doctor will decide whether you should take Hydroxychloroquine Sulfate Tablets during this time.

Driving and using machines

When you first start treatment with Hydroxychloroquine Sulfate Tablets you may get blurred vision. If this happens do not drive a car or operate machinery. If this continues or you get other visual problems see your doctor immediately. There is more information on this in section 4.

Hydroxychloroquine Sulfate Tablets contain 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 Tablets

Always take Hydroxychloroquine Sulfate Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you

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are not sure. Your doctor will decide the right dose for you; this will be on the pharmacist's label. Check this carefully, it will tell you how many tablets to take and how often to take them.

Taking this medicine

- swallow the tablets whole with a meal or a glass of milk
- the doctor will work out the dose depending on your body weight
- if you are being treated for a skin disease that is sensitive to sunlight light, then you should use this medicine during periods of high exposure to light
- while you are taking this medicine your doctor may arrange for blood tests to monitor your response to treatment
- if you have been taking this medicine for more than 6 months and you do not feel that it is helping you, speak to your doctor as it may be decided to stop treatment with this medicine.

How much to take

Adults (including older people)

- the usual dose is one tablet taken daily or one tablet taken morning and night
- your doctor may alter your dose depending on your response to treatment.

Children and Adolescents

- one tablet each day
- this medicine is only suitable for children who weigh more than 31kg.

It may be several weeks before you notice an improvement in your condition with this medicine.

The score line is not intended for breaking the tablet.

If you take more Hydroxychloroquine Sulfate Tablets than you should

If you (or anybody else), takes more Hydroxychloroquine Sulfate Tablets then you should contact your nearest hospital casualty department or doctor immediately. Always take the blister pack of tablets and this leaflet with you.

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

Symptoms that could indicate someone has taken too much are headache, visual disturbances, breathing difficulties, problems with your heart, low blood pressure and fits.

If you forget to take Hydroxychloroquine Sulfate Tablets

If you forget a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. NEVER take a double dose to make up for the one missed.

4. Possible side effects

Like all medicines, Hydroxychloroquine Sulfate Tablets can cause side effects, although not everybody gets them.

If you experience any of the following symptoms, then stop taking the medicine and seek medical help immediately:

- rash, itching and/or difficulty breathing
- rapid swelling of the skin around the face, particularly the mouth
- blistering of the skin, particularly the mouth, face, nose and genitals, fever and flu-like symptoms. This could be a serious reaction called Stevens - Johnson syndrome
- other skin changes including the formation of numerous small pustules or itchy pink-red blotches or generalised scaling of the skin
- fits

If you experience any of the following symptoms then stop taking the medicine and tell your doctor immediately:

- 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
- any visual disturbance including persistent blurring of vision, changes to your colour vision, or sensitivity to light
- any muscle weakness, particularly of the upper arms or legs, muscle spasms or cramps, or changes in sensation of your skin. If you take this medicine over a long time your doctor will occasionally check your muscles and tendons to ensure they are not affected
- weakening of the heart muscle (cardiomyopathy) resulting in difficulty breathing, chest pain, an irregular or abnormal heartbeat, feeling dizzy or tired, swelling of feet, ankles and legs.
- unexpected bleeding or bruising, tiredness and pale skin, or frequent signs of infection such as sore throat, mouth ulcers and fever
- stiffness, abnormal movements or shaking

You should tell your doctor or pharmacist if you have any of the following side effects, or if you think Hydroxychloroquine Sulfate Tablets are making you feel unwell in any other way.

Side effects reported with this medicine include:

Very Common (may affect more than 1 in 10 people):
stomach pains; feeling sick (nausea)

Common (may affect more than 1 in 100 people):
itchy raised rash; diarrhoea; being sick (vomiting); headache; loss of appetite; mood swings

Uncommon (may affect more than 1 in 1000 people):
changes in the colour of skin or the inside of the nose or mouth; bleaching of hair / hair loss; dizziness; decreased reflexes; abnormal liver function seen on blood tests; vertigo; ringing in the ears; nervousness

Not Known (frequency cannot be estimated):
abnormal nerve conduction; liver failure; symptoms of a condition called Porphyria, which may include stomach pain, being sick, constipation, fits, rashes or blisters, itching, pain or weakness in back, arms and legs; problems with heart conduction system; hearing loss; psychosis; feeling depressed or having thoughts of self-harm or suicide; hallucinations; feeling nervous or anxious; feeling confused; agitated; difficulty sleeping; feeling elated or overexcited.

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 report side effects directly via 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 store above 25°C. Store in the original packaging; do not transfer your tablets to another container
- Do not take after the expiry date on the label; the expiry date refers to the last day of the month.

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

6. Contents of the pack and other information

What Hydroxychloroquine Sulfate Tablets contain

The active ingredient is: 200 mg hydroxychloroquine sulfate. The other ingredients are: lactose monohydrate, maize starch, hypromellose, croscarmellose sodium, magnesium stearate, talc, titanium dioxide, macrogol 6000, iron oxide yellow E172 and polysorbate 80.

What Hydroxychloroquine Sulfate Tablets look like and contents of the pack

Hydroxychloroquine Sulfate Tablets are round, light yellow tablets with a score line on one side and Incepta inscribed on the reverse. They are supplied in blister pack of 10 tablets, with an outer cardboard carton, and are available in pack size of 28, 30 or 60 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Blackrock Pharmaceuticals Ltd
The Old Barrel Store, Brewery Courtyard
Draymans Lane, Marlow
SL7 2FF, United Kingdom

Product Licence Number: PLGB 33271/0017

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