

Package leaflet: Information for the user

Hydroxychloroquine sulfate Aurobindo 200 mg, film-coated tablets hydroxychloroquine sulfate

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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

Hydroxychloroquine sulfate Aurobindo contains the active substance hydroxychloroquine sulfate.

The medicine is used for:

Adults

for the treatment of a disease that is chronic and causes inflammation of joints, muscles, tendons, or ligaments (rheumatoid arthritis)
against certain diseases that cause symptoms such as skin problems and/or joint complaints (systemic and discoid lupus erythematosus)
against certain types of skin rashes caused by sunlight. Or that worsen due to sunlight (photodermatoses)
for the treatment of sudden attacks of malaria. And to ensure that you do not get malaria.

Children (6 years or older and 31 kilograms or heavier)

for the treatment of juvenile arthritis in combination with other treatments.
against certain diseases that cause symptoms such as skin problems and/or joint complaints (systemic and discoid lupus erythematosus).
for the treatment of sudden attacks of malaria. And to ensure that you do not get malaria.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to hydroxychloroquine or 4-aminoquinoline compounds (other antimalarial drugs) or any of the other ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.
- If you have an eye problem that damages the retina or the inside of the eye (maculopathy). Or if the color of your eye changes. Or if you develop another eye problem.
- You have a certain muscle disease. Your muscles are then very weak (myasthenia gravis).
- This medicine should not be used by children younger than 6 years and lighter than 31 kilograms.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine:

- if you suffer from problems with your nervous system.
- if you suffer from a disease of the stomach and intestines. Or a blood disease.
- if you suffer from a disease called porphyria. This medicine can worsen that disease. Are you using this medicine for a long time? Then your blood will be regularly monitored.
- if you have an infection with the hepatitis B virus without symptoms but that does not go away.
- if you have liver problems or kidney problems.
- if you have a hereditary disease called 'glucose-6-dehydrogenase deficiency'.
- if you have a skin disease that causes red, scaly patches on the skin. Usually on the knees, elbows, and scalp (psoriasis) (see section 4). Your doctor will be cautious when prescribing this medicine.
- if you are hypersensitive to quinine.

Your doctor will examine your eyes for abnormalities before you start using this medicine. Are you using this medicine for a long time? Then this eye examination will be repeated. Do you experience vision problems while using this medicine? For example, do you see less sharply? Or do you think your field of vision is getting smaller? Or do you see colors less well? Then contact your doctor immediately. It is not advised to use Hydroxychloroquine sulfate Aurobindo together with medicines that are harmful to the retina (such as tamoxifen).

This medicine can cause heart rhythm disorders in some patients. Be cautious with the use of this medicine:

- if you were born with a hereditary heart rhythm disorder (a prolonged QT interval). Or if you have family members with a prolonged QT interval,
- if you have QT prolongation. This can be seen on an electrocardiogram (ECG),
- if you have a heart disease. Or if you have had a heart attack (myocardial infarction) in the past,
- if the balance of salt in your blood is disturbed. Especially a low amount of potassium or magnesium,
- if you are using medicines that affect your heart rhythm (see section "Are you using any other medicines?").

Do you experience palpitations? Or do you get an irregular heartbeat during treatment? Then contact your doctor immediately. The risk of heart problems may increase with higher dosages. Therefore, use the recommended dosage.

After using this medicine, you may experience the problem that your heart pumps your blood less effectively (heart failure). In a few cases with a fatal outcome. Symptoms of heart failure include being tired, shortness of breath, and swollen legs and ankles. Contact your doctor if you experience these symptoms.

This medicine can cause low blood sugar (hypoglycemia). Do you notice that you are experiencing symptoms? Such as sweating, trembling, dizziness, sudden mood changes, being easily distracted, headache, tiredness, hunger? Or if you lose consciousness? Then contact your doctor to have your blood sugar levels checked.

Are you using this medicine for a long time? The function of your muscles and tendons should then be regularly monitored. Do you experience weak muscles or tendons? Talk to your doctor. Your doctor may decide to stop the treatment.

This medicine can cause movement problems (extrapyramidal symptoms) (see section 4 "Possible side effects").

Some people using hydroxychloroquine may experience mental health problems. Such as irrational thoughts, anxiety, seeing, feeling, or hearing things that are not there (hallucinations), being confused or depressed. Along with thoughts of self-harm or suicide. Even people who have never had problems like these before. Do you or others around you notice any of these side effects (see section 4 "Possible side effects")? Then seek medical advice immediately.

Severe skin rash has been observed with the use of hydroxychloroquine (see section 4 "Possible side effects"). This rash often involves sores in the mouth, throat, nose, genitals, and red and swollen eyes (conjunctivitis). You may first experience flu-like symptoms such as fever, headache, and body aches before developing this rash. The rash can further cause blisters all over the body and peeling of the skin. Do you experience these skin problems? Then stop using this medicine and contact your doctor immediately.

Children

This medicine should not be used in children under 6 years and lighter than 31 kilograms. Young children are particularly sensitive to the toxic effects of quinolones. Keep this medicine out of the reach of children.

Are you using any other medicines?

Are you taking any other medicines besides Hydroxychloroquine Aurobindo, have you recently taken any, or are you planning to take any soon? Then tell your doctor or pharmacist.

Medicines that affect your heart rhythm. This also applies to medicines used for:

- an abnormal heart rhythm (antiarrhythmics)
- depression (tricyclic antidepressants)
- psychiatric problems (antipsychotics)
- bacterial infections (e.g., moxifloxacin, azithromycin)
- HIV treatment (e.g., saquinavir)
- fungal infections (e.g., fluconazole)
- parasitic infections (e.g., pentamidine)
- or against malaria (e.g., halofantrine).

Medicines for diabetes (such as insulin or metformin). Hydroxychloroquine Aurobindo can increase the effect of these medicines on blood sugar levels. It may therefore be necessary to reduce their dosage.

Rabies vaccine. Hydroxychloroquine Aurobindo can reduce the effectiveness of this vaccine. Are you using Hydroxychloroquine Aurobindo? Then it is not recommended to inject the rabies vaccine into the skin. If the vaccine is injected into a muscle, the protection is sufficient.

Certain medicines for the treatment of depression (MAO inhibitors). Do not combine these medicines with Hydroxychloroquine Aurobindo.

Medicines for malaria (such as mefloquine). These medicines can increase the risk of seizures.

Medicines for epilepsy (seizures), such as phenobarbital, phenytoin, carbamazepine. The effect of these medicines (antiepileptics) can change when taken together with Hydroxychloroquine Aurobindo.

Antacid inhibitors (for heartburn) and kaolin: Ensure there is at least 2 hours between taking Hydroxychloroquine Aurobindo and antacids and/or kaolin.

Cimetidine (used for stomach ulcers).

Medicines for infections caused by bacteria (such as rifampicin, clarithromycin).

Medicines for infections caused by fungi (such as itraconazole).

Medicines that lower the fats in your blood (such as gemfibrozil, statins).

Medicines for the treatment of HIV (such as ritonavir).

Medicines used in surgeries where you receive a new organ. Or for complaints of your body's immune system (such as ciclosporin).

Medicines for depression (fluoxetine, paroxetine).

Blood thinners (such as dabigatran, clopidogrel).

Medicines for heart diseases (such as digoxin, flecainide, propafenone, quinidine, and metoprolol).

St. John's wort (an herbal treatment for depression).

What should you pay attention to with food and drink?

Do not drink grapefruit juice. This can increase the risk of side effects.

Pregnancy and breastfeeding and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Pregnancy

This medicine can slightly increase the risk of serious malformations. Do not use this medicine during pregnancy unless your doctor thinks the benefits of using this medicine outweigh the risks.

Prevention and treatment of malaria

Does your doctor think the benefits of using this medicine outweigh the risks? This medicine can then be used to ensure that you do not get malaria. And for the treatment of malaria infections. This is because a malaria infection itself is harmful to an unborn baby.

Breastfeeding

This medicine passes into breast milk. Young children are very sensitive to the side effects of this medicine.

Prevention and treatment of malaria

Are you breastfeeding? Your doctor will then decide whether you can use this medicine. This depends on the condition and the duration of the treatment.

Are you using this medicine to ensure that you do not get malaria? Then you do not need to stop breastfeeding. But the amount of hydroxychloroquine your baby receives through breast milk is insufficient to ensure that your baby does not get malaria.

Rheumatoid arthritis and lupus erythematosus

Are you using a high dosage of this medicine for a long time? Then stop breastfeeding.

Fertility

There is no known information about the influence of hydroxychloroquine on human fertility.

Driving ability and the use of machines

You may experience eye problems and dizziness while using this medicine. Does this happen? Do not drive vehicles or use machines. Contact your doctor immediately.

Hydroxychloroquine Aurobindo contains lactose monohydrate

Has your doctor told you that you cannot have certain sugars? Then contact your doctor before taking this medicine.

3. How do you take this medicine?

Always take this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Preferably take tablets of this medicine after a meal.

The recommended dosage is:

For adults

A certain type of rheumatism (rheumatoid arthritis) Initial dosage: 2 tablets per day. Maintenance dosage: 1 tablet per day. Later possibly 1 tablet every other day.

A disease where your immune system does not function properly. Your body makes itself sick (systemic and discoid lupus erythematosus)

Initial dosage: 2-3 tablets per day.

Maintenance dosage: 1-2 tablets per day.

Skin complaints due to sunlight

The treatment is only necessary if you are frequently in the light. For adults: 2 tablets per day is usually sufficient.

To prevent malaria

Adults: 2 tablets per week. Take these on the same day each week. You should start the treatment 1 week before traveling to a malaria area. Continue the treatment for 4 to 8 weeks after leaving that area. This ensures you do not get malaria.

Treatment of malaria

In case of a sudden malaria attack, the dose is determined by the severity of the infection. The total dose is a maximum of 2 grams. You receive this over a period of up to 3 days.

For children

Your doctor determines the dose by checking how much you weigh. Children weighing less than 31 kilograms should not take the 200 milligram tablet.

Your liver or kidneys are not functioning as well as normal

Are your kidneys or liver not functioning as well as normal? Your doctor may give you a lower dose.

Duration of the treatment

Your doctor will tell you how long the treatment will last for you. Are you receiving this medication for a long time? Then your doctor will give you the lowest possible dosage. Are you receiving this medication for the treatment of joint complaints? Then this medication needs several weeks to work as effectively as possible.

Taking this medication

Take this medication orally.

Swallow the tablets whole after a meal.

Take the tablets once a day. Or divide the tablets over 2 or 3 times a day.

Are you using this medicine for skin problems that are sensitive to sunlight? Then only take this medicine when you are frequently in the light.

Your doctor determines the dose by looking at how much you weigh. Do you feel that your medicine is not working well or is working too well? Then do not change your dose yourself, but ask your doctor.

Have you been using this medicine for a long time for a certain type of rheumatism (rheumatoid arthritis)? And is that more than 6 months? And do you not feel that the medicine is helping you? Then contact your doctor. This is because the treatment may need to be stopped.

Have you taken too much of this medicine?

Have you used more of this medicine than you should have? Then tell your doctor. Or go immediately to the emergency department of a hospital. Take the medicine with you.

This way your doctor knows what you have taken. You may experience the following symptoms: headache, vision problems, drop in blood pressure, convulsions (seizures), heart problems causing an irregular heartbeat, then sudden severe breathing problems and possibly a heart attack. An overdose of this medicine can be fatal.

Especially young children and babies are at risk if they accidentally take this medicine. Does this happen? Then take the child or baby immediately to a hospital.

Have you forgotten to take this medicine?

Did you forget a dose? Then take it as soon as you remember. Is it almost time for the next dose? Then skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

Continue taking your medicine until your doctor tells you to stop. Do not stop taking this medicine just because you feel better. If you stop, your illness may worsen again.

Do you have any other questions about using this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can also have side effects. Not everyone will experience them.

Some side effects are serious. Do you experience any of the following side effects? Then stop using this medicine. Contact your doctor or go directly to a hospital.

Rare (occur in less than 1 in 1,000 users)

Eye problems. Including changes in the color of your eye and vision problems. Such as blurred vision, sensitivity to light, or changes in color perception. Do you notice these problems early enough? Then they usually decrease after stopping treatment with this medicine. Do you notice the problems later? Then the problems may still persist. Or even worsen after stopping the treatment.

Seizures (convulsions).

Weakening of the heart muscle (cardiomyopathy). This can cause heart failure and be fatal. Symptoms include feeling tired, shortness of breath, and swollen legs and ankles.

Not known (cannot be determined from the available data)

Severe skin reactions (see section 2 "When should you be extra careful with this medicine?") such as:

- Rash with fever and flu-like symptoms and enlarged lymph nodes. This may be a condition called drug reaction with eosinophilia and systemic symptoms (DRESS).
- Blisters, a scaly skin over a large part of the body, pus-filled spots along with fever. This may be a condition called acute generalized exanthematous pustulosis (AGEP).
- Blisters or peeling skin around the lips, eyes, mouth, nose, and genitals, flu-like symptoms, and fever. This may be a condition called Stevens-Johnson syndrome (SJS).
- Multiple skin lesions, itching of the skin, joint pain, fever, and a general feeling of being unwell. This may be a condition called toxic epidermal necrolysis (TEN).
- Skin reactions. Including purple, painful sores on the skin, especially on your arms, hands, fingers, face, and neck, which also come with fever. This may be a condition called Sweet's syndrome.

If you have an eye problem that damages the inside of the eye (the retina) (maculopathy).

If you feel weak, tired, faint, or dizzy, have pale skin, or are short of breath. Or you bruise more easily than normal. Or you get infections more easily than normal, such as fever, severe chills, sore throat, or mouth ulcers. These may be signs of blood disorders called anemia, aplastic anemia, thrombocytopenia, leukopenia, or agranulocytosis.

Liver problems. Symptoms may include a general feeling of being unwell, with or without a yellowing of the skin and eyes (jaundice), dark urine, nausea, vomiting, and/or abdominal pain. Rare cases have been seen where the liver no longer functions properly (liver failure). Including fatal cases.

Too little sugar (glucose) in your blood (hypoglycemia). You may feel nervous, shaky, or sweaty.

A heart rhythm different from normal, life-threatening irregular heart rhythm (visible on an ECG). See section 2 "When should you be extra careful with this medicine?".

Other side effects associated with hydroxychloroquine sulfate

Common side effects (occur in less than 1 in 10 users)

You have less appetite (anorexia).

You are first very happy and then very sad.

Sometimes occurring side effects (occur in less than 1 in 100 users)

Being nervous.

Nausea, diarrhea, and abdominal pain. These complaints usually disappear after reducing the dose. Or after stopping the treatment.

Skin rash.

Rare side effects (occur in less than 1 in 1,000 users)

The function of the bone marrow is less effective than normal (myelosuppression).

Severe psychological complaints. You have little or no control over your own behavior and actions (psychosis).

Vomiting (this usually disappears after reducing the dose or stopping the treatment).

Very rare side effects (occur in less than 1 in 10,000 users)

Hearing loss (permanent).

A red skin with irregular spots that lie on the skin (erythema multiforme).

This medicine is very similar to the substance chloroquine phosphate. A long treatment with that substance can very rarely cause reversible phospholipidosis (increased accumulation of intracellular phospholipids), including renal phospholipidosis. Because the two substances are very similar, this side effect may also be associated with hydroxychloroquine. Are your kidneys already functioning less well? Then the function of the kidneys may worsen.

Side effects with unknown frequency (cannot be determined from the available data)

A disease of the red blood cells worsens (porphyria).

Being sleepy/dizzy.

You become angry or sad more quickly.

Ringing in the ears (tinnitus).

Headache.

Movement problems (extrapyramidal disorders) such as being stiff (dystonia), unusual movements (dyskinesia), or shaking (tremor) of the body muscles.

Changes in the retina, problems with your visual field, where you do not see parts of your visual field (with paracentral rings, everything next to the center of the visual field is visible, with pericentral rings, only the center of the visual field is visible), temporary blind spots in your visual field, and seeing colors differently than normal.

Changes in the cornea. Such as cloudiness or your cornea retaining fluid have been observed. Sometimes you do not experience symptoms from these changes. But you may also experience vision problems. Such as seeing colored rings, blurred vision, or photophobia. These problems are temporary or improve after stopping the treatment. Blurred vision because your eye focuses less well. This problem is temporary and improves when the dose is reduced.

Changes in heart rhythm. Your doctor checks the electrical activity of your heart with an electrocardiogram (ECG).

Both heart chambers are larger than normal (biventricular hypertrophy).

Unusual liver function test results.

Severe liver failure.

Itching (pruritus), changes in the color of your skin. Or the inside of your nose or mouth, hair loss, or loss of hair color. These complaints usually disappear after reducing the dose. Or after stopping the treatment.

Skin rash with blisters or bumps.

Sensitivity to light (photosensitivity).

An inflammation of the skin. Your skin is red and you may experience scaling (exfoliative dermatitis).

A recurring skin disease where you suffer from scaling, dry skin rash (psoriasis).

Skin rash with pink bumps and severe itching (hives), difficulty breathing.

Muscle diseases (myopathy of skeletal muscles or neuromyopathy) that cause you to become progressively weaker. And cause a reduction in your muscle strength (atrophy). Stop the treatment with this medication? Then your muscles can recover.

This can take a few months.

Allergic reactions. Such as skin rash with severe itching and the formation of bumps (urticaria). And swelling of the skin or mucous membranes with itching (angioedema).

You are short of breath due to cramping of the muscles of the bronchi (bronchospasms).

Feeling depressed. Or thoughts of self-harm or suicide, seeing, feeling, or hearing things that are not there (hallucinations), being nervous or anxious, being confused, nervous, excited or restless, having trouble sleeping, being enthusiastic or very excited.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find this on the label, the box, or the bottle after "Exp.". It includes a month and a year. The last day of that month is the expiry date.

This medicine has no special storage conditions.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

- The active substance in this medicine is hydroxychloroquine sulfate.
Each film-coated tablet contains 200 milligrams of hydroxychloroquine sulfate.

- The other substances in this medicine are:
Tablet core: lactose monohydrate, corn starch, magnesium stearate.
Film coating: hypromellose 2910 (E464), titanium dioxide (E171), macrogol 400 (E1521).

What does Hydroxychloroquine Sulfate Aurobindo look like and what is in a package?

Film-coated tablet.

White, oval, biconvex, approximately 12.8 x 6 mm size film-coated tablets with inscription "HC" on one side and "200" on the other side.

Hydroxychloroquine Aurobindo film-coated tablets are available in blister packs and HDPE bottle.

Package sizes:

Blister pack: 30, 90, and 100 film-coated tablets. HDPE bottle: 500 film-coated tablets.

It is possible that not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder:

Aurobindo Pharma B.V.

Baarnsche Dijk 1

3741 LN Baarn

Netherlands

Manufacturer:

APL Swift Services (Malta) Ltd.

HF26 Hal Far Industrial Estate, Hal Far

Birzebbugia BBG 3000

Malta.

Generis Farmaceutica S.A.

Rua Joao De Deus N 19, Venda Nova

2700-487 Amadora

Portugal

Registered under RVG 133502

This medicine is registered in member states of the European Economic Area under the following names:

Germany: Hydroxychloroquin PUREN 200 mg Filmtabletten

Italy: Hydroxychloroquine Aurobindo

Netherlands: Hydroxychloroquinesulfaat Aurobindo 200 mg, film-coated tablets

Portugal: Hydroxychloroquine Generis

Spain: Hydroxychloroquine Aurovitas 200 mg EFG film-coated tablets

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