

Package leaflet: Information for the user

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

What is in this leaflet

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

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

Hydroxychloroquine sulfate Accord contains the active substance hydroxychloroquine sulfate. It can be used for:

Adults

- for the treatment of a chronic condition with inflammation of joints, muscles, tendons or ligaments (rheumatoid arthritis).
- against certain diseases that manifest themselves by, among other things, skin problems and / or joint complaints (discoid and systemic lupus erythematosus).
- for the treatment of skin problems which are sensitive to sunlight (photodermatoses).
- for the treatment of acute attacks of malaria and to prevent malaria.

Children (≥ 6 years and ≥ 31 kg)

- For the treatment of childhood rheumatism in combination with other treatments (Juvenile idiopathic arthritis)
- Against certain diseases that manifest themselves by, among other things, skin problems and / or joint complaints (Discoid and systemic lupus erythematosus)
- For the treatment of acute attacks of malaria and to prevent malaria

2. What you need to know before you take Hydroxychloroquine sulfate Accord

Do not take Hydroxychloroquine sulfate Accord if:

- You are allergic to:
 - hydroxychloroquine sulfate or any of the other ingredients of this medicine (listed in section 6 below). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
 - other similar medicines such as quinolones and quinine (other medicines used for malaria).

- 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
- If you suffer from a pigmented retinal disease (retinitis pigmentosa).
- You are suffering from a certain form of muscle weakness (myasthenia gravis).
- Hydroxychloroquine sulfate Accord should not be used in children under 6 years of age and below 31 kg.

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 Accord.

Warnings and precautions

Talk to your doctor or pharmacist before taking Hydroxychloroquine sulfate Accord if:

- You have liver or kidney 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 heart problems (signs include breathlessness and chest pain) which may require monitoring.
- 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.
- You have an inactive chronic infection with hepatitis B virus
- 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.
- Some people being treated with Hydroxychloroquine sulfate Accord 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.
- Serious skin rashes have been reported with the use of hydroxychloroquine (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 and contact your doctor immediately.
- Hydroxychloroquine sulfate Accord may cause heart rhythm disorders in some patients: caution should be taken when using Hydroxychloroquine sulfate Accord, if you were born with or have family history of prolonged QT interval, if you have acquired QT prolongation (seen on ECG, electrical recording of the heart), if you have heart disorders or have a history of heart attack (myocardial infarction), if you have salt imbalance in the blood (especially low level of potassium or magnesium, see section “Other medicines and Hydroxychloroquine sulfate Accord”). If you experience palpitations or irregular heart beat during the period of treatment, 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.

Before treatment with Hydroxychloroquine sulfate Accord

- Before you start taking this medicine your doctor will examine your eyes to determine if there are any abnormalities. This eye examination should be repeated with prolonged use of this medicine, at least every 6 months whilst taking Hydroxychloroquine sulfate Accord.

- 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.

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

Children

Hydroxychloroquine sulfate Accord should not be used in children under 6 years of age and below 31 kg. Small children are particularly sensitive to the toxic effect of quinolones, so Hydroxychloroquine sulfate Accord should be kept out of the reach of children.

Other medicines and Hydroxychloroquine sulfate Accord

Please tell your doctor or pharmacist if you are taking, have recently taken or might use any other medicines, including medicines obtained without a prescription. This includes in particular.

- Insulin or other medicines for diabetes
- Medicines for malaria such as mefloquine, halofantrine (as it may increase the risk of seizures)
- Medicines for epilepsy (seizures), in particular phenobarbital, phenytoin, carbamazepine
- Medicines that affect the skin, the blood or the eyes
- Tamoxifen, used to treat breast cancer
- Agalsidase (used for a rare disease named “Fabry disease”)
- Medicines for bacterial infections (such as rifampicin, clarithromycin, moxifloxacin, macrolides including azithromycin, roxithromycin, spiramycin and those named “aminosides” such as gentamicin, neomycin or tobramycin)
- Cimetidine - used for stomach ulcers
- Neostigmine and pyridostigmine - used for muscle weakness (myasthenia gravis)
- Rabies vaccine
- Medicines that may affect the kidney or liver
- Antacid medicines (for heartburn) and kaolin: Take Hydroxychloroquine sulfate Accord at least 2 hours apart from those.
- Medicines for fungal infections (such as itraconazole, fluconazole)
- Medicines for lipid disorders (such as gemfibrozil)
- Medicines for HIV treatment (such as saquinavir, ritonavir)
- Medicines for organ transplantation or immune system disorders (such as ciclosporin)
- Medicines for blood clots (such as dabigatran, clopidogrel)
- Medicines for heart diseases (such as digoxin, flecainide, propafenone, and metoprolol)
- Praziquantel, pentamidine (an antiparasitic medicine)
- Medicines for depression (fluoxetine, paroxetine)
- an herbal treatment for depression: St. John’s wort.

Hydroxychloroquine sulfate Accord with food and drink

Avoid taking grapefruit juice as it may increase the risk of side effects.

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. Your doctor will discuss with you whether Hydroxychloroquine sulfate Accord is suitable for you.

Pregnancy

Hydroxychloroquine sulfate Accord may be associated with a small increased risk of major malformations and should not use Hydroxychloroquine sulfate Accord during pregnancy in high daily doses unless your doctor says this is necessary because the risk of stopping treatment is greater than the potential risk to the fetus.

This medicine can be used during pregnancy to prevent malaria, as only low doses are required.

Breast-feeding

This medicine is excreted in breast milk. There is insufficient information about the effects of hydroxychloroquine in newborns / infants. Depending on the condition and duration of treatment, your doctor will decide whether you can use this medicine during breast-feeding. When you take this medicine once per week, such as to prevent malaria, you do not have to stop breast-feeding. This amount however is insufficient to prevent malaria in the infant.

Driving and using machines

You may get eye problems and dizziness while taking this medicine. If this happens, do not drive or use any tools or machines, and tell your doctor straight away.

Hydroxychloroquine sulfate Accord contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Hydroxychloroquine sulfate Accord

Always take this medicine exactly as your doctor or pharmacist has told you. Your doctor will decide your daily dose. Check with your doctor or pharmacist if you are not sure.

How much to take

The recommended dose is:

For Adults

- *Rheumatoid arthritis*
- Starting dose: 2 tablets per day.
- Maintenance dose: 1 tablet per day, later possibly 1 tablet every other day.

Systemic and discoid lupus erythematosus

Starting dose: 2-3 tablets per day.

Maintenance dose: 1-2 tablets per day.

Skin conditions due to sunlight

The treatment is limited to those periods in which you are exposed to a lot of light.

For adults: 2 tablets per day is usually enough.

Preventing malaria

Adults: 2 tablets per week on the same day of each week. In the prevention of malaria, you must receive treatment for one week before arrival in the malaria area and continue it for four weeks after departure from that area.

Treatment of malaria

The dose in case of an acute attack of malaria depends on the nature of the infection. The total dose is a maximum of 2 grams 10 tablets and is administered over a maximum of three days.

For children

Your doctor will determine the dose based on body weight. The 200 mg tablet is not suitable for children with a body weight of less than 31 kg.

Reduced kidney and liver function

If you have impaired kidney or liver function, your doctor may prescribe a lower dose.

Duration of treatment

Follow your doctor's instructions regarding the duration of treatment. Your doctor will give the lowest possible dose for a long-term treatment with this medicine. When treating joint disorders, this medicine needs a few weeks to get the best effect.

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.
- The tablets can be taken once a day or the tablets can be divided on two or three times during the day.
- If you are taking this medicine for skin problems that are sensitive to sunlight, only take Hydroxychloroquine sulfate Accord 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 Accord than you should

- If you take more Hydroxychloroquine sulfate Accord than you should, tell a doctor or go to a hospital casualty department **straight away**. Take the medicine 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. Overdose of Hydroxychloroquine sulfate Accord may have a fatal outcome.
- Young children and babies are particularly at risk if they accidentally take Hydroxychloroquine sulfate Accord. Take the child to a hospital straight away.

If you forget to take Hydroxychloroquine sulfate Accord

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 dose.

If you stop taking Hydroxychloroquine sulfate Accord

Keep taking your medicine until your doctor tells you to stop. Do not stop taking Hydroxychloroquine sulfate Accord 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 product, 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 Accord and see a doctor or go to a hospital straight away if:

- 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.

Stop taking Hydroxychloroquine sulfate Accord 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 problems with your eyesight such as blurring

Uncommon (may affect up to 1 in 100 people):

- You have any eye problems such as sensitivity to light or the way you see and change in the colour of your eye
- You have any muscle weakness, cramps, stiffness or spasms or changes in sensation such as tingling which can lead to difficulty in moving

Not known (frequency cannot be estimated from available data):

- 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-colored, 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's syndrome.
 - Severe red scaly rash, skin bumps that contain pus, blisters or peeling of skin, which may be associated with a high fever and joint pain. This could be a condition called Erythema multiforme
 - sunburn-like reactions (following exposure to light)
- Having thoughts of self-harm or suicide (see section 2 Warnings and precautions).
- You have an eye problem which affects the retina, the inside of the eye (maculopathy)
- 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 get infections more easily than usual. This could be due to bone marrow depression or a blood disorder called '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'
- 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.
- Abnormal heart rhythm, life-threatening irregular heart rhythm (seen on ECG) (see section Warnings and precautions)
- 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

Rare (may affect up to 1 in 1,000 people)

- Eye problems including changes in the colour of your eye and problems with your eyesight such as blurring, sensitivity to light or the way you see colours. If these problems are noticed early, they will usually be less after treatment with Hydroxychloroquine sulfate Accord is stopped. If the problems are not noticed until later, the problems may still exist or even get worse after stopping treatment.
- Fits/seizures
- Difficulty breathing, coughing, high blood pressure, swelling, increased heart rate, low amount of urine - these may be signs of weakening of the heart muscle (cardiomyopathy or heart failure) and may be fatal.

Other side effects associated with hydroxychloroquine sulfate

Common (may affect up to 1 in 10 people)

- Decreased appetite (anorexia).

Uncommon (may affect up to 1 in 100 people)

- Nausea, diarrhoea and abdominal pain. These symptoms usually disappear after lowering the dose or stopping treatment.
- Skin rash.

Rare (may affect up to 1 in 1,000 people)

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

Very rare (may affect up to 1 in 10,000 people)

- Hearing loss (permanent).
- Redness of the skin with raised irregular spots (erythema multiforme).
- Long-term therapy with hydroxychloroquine may lead to increased accumulation of phospholipids in tissues, also in the kidney. If your kidney function is already impaired, it may get worse.

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

- Worsening of a red blood cell disorder (porphyria).
- Drowsiness/vertigo.
- Ringing in the ears (tinnitus).
- Headache.
- Temporary blind spots in the field of view and abnormal colour observations; temporary blurred vision or sensitivity to light.
- Problems with the skin such as severe itching of the skin, skin rash with blisters or bumps, hypersensitivity to light, redness and peeling, flaking dry skin rash, changes in the colour of your skin or the inside of your nose or mouth, hair loss or the loss of hair colour.
- Movement disorders such as muscular tension.
- Disease of the muscle causing muscular weakness.
- Changes in sensory perception or in control of extremities; reduced tendon reflexes.
- Breathing difficulties.
- Abnormal liver function test results.
- Serious liver failure.
- Allergic reactions such as skin rash with severe itching and formation of bumps (urticaria).
- Heart problems.
- Abnormal heart beat (seen on ECG) (see section 2, "Before treatment with Hydroxychloroquine sulfate Accord").
- Mental problems (such as delusions, hallucinations and changes in mood).

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

HPRA Pharmacovigilance,

Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hydroxychloroquine sulfate Accord

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 blister or carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 to protect the environment.

6. Contents of the pack and other information

What Hydroxychloroquine sulfate Accord contains

- Each tablet contains 200 mg of the active substance, hydroxychloroquine sulfate.
- The other ingredients are lactose monohydrate, maize starch, magnesium stearate (E470b), povidone (E1201), polyvinyl alcohol (E1203), talc (E553b), macrogol and titanium dioxide (E171).

What Hydroxychloroquine sulfate Accord looks like and contents of the pack

Hydroxychloroquine sulfate Accord 200 mg film-coated tablets are white to off-white, peanut shaped, biconvex, film-coated tablets debossed with “H11” on one side and plain on the other side.

Approximate dimension is $12.80 \pm 0.05 \text{ mm} \times 6.10 \pm 0.05 \text{ mm}$.

They are supplied in blister pack of 20, 30, 50, 60, 90 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturer

Accord Healthcare Polska Sp.z o.o.
ul. Lutomska 50,
95-200 Pabianice
Poland

This medicine is authorised in the Member States of the European Economic Area under the following names:

Name of the Member State	Name of the Medicine
Cyprus	Hydroxychloroquine sulfate Accord 200 mg film-coated tablets
Spain	Hidroxicloroquina Accord 200 mg comprimido recubierto con película EFG
Italy	Redros /Xiclor / Reclor
Portugal	Hydroxychloroquine sulfate Accord
Ireland	Hydroxychloroquine sulfate Accord 200 mg film-coated tablets
Germany	Hydroxychloroquin Accord 200 mg Filmtabletten
Denmark	Hydroxychloroquinsulfat Accord
Estonia	Hydroxychloroquine sulfate Accord
Lithuania	Hydroxychloroquine sulfate Accord 200 mg plėvele dengtos tabletės
Latvia	Hydroxychloroquine sulfate Accord 200 mg apvalkotās tabletes
Netherlands	Hydroxychloroquinesulfaat Accord 200 mg filmomhulde tabletten
Norway	Hydroxychloroquine sulfate Accord

Sweden	Hydroxychloroquine Accord
Bulgaria	Hydroxychloroquine sulfate Accord 200 mg Филмирана таблетка
Czech Republic	Hydroxychloroquine sulfate Accord
Poland	Hydroxychloroquine sulfate Accord
Romania	Sulfat de hidroxichlorochină Accord 200 mg comprimate filmate
Hungary	Hydroxychloroquine sulfate Accord 200 mg filmtabletta
Slovenia	Hidroksiklorokinjev sulfat Accord 200 mg filmsko obložene tablete

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