

QUINNEL 200 MG FILM-COATED TABLET

Hydroxychloroquine Sulfate (200 mg)

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What QUINNEL is used for

QUINNEL is used in the treatment of:

- Rheumatoid arthritis (inflammation of the joints characterized by stiffness, swelling and pain) in adult and children.
- Discoid and systemic lupus erythematosus (where the immune system attacks the body causing tissue damage and inflammation).
- Skin problems that are triggered or worsened by sunlight.

How QUINNEL works

QUINNEL contains the active ingredient Hydroxychloroquine sulfate. It works by reducing inflammation and thus can reduce pain, swelling and joint stiffness.

Before you use QUINNEL

- When you must not use it

Do not take QUINNEL if:

- You are allergic (hypersensitive) to hydroxychloroquine sulfate or 4-aminoquinoline compounds (e.g. chloroquine, amodiaquine) or any of the other ingredients in the formulation.
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of 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.

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 QUINNEL.

- Before you start to use it

Talk to your doctor or pharmacist before taking QUINNEL if:

- You have liver or kidney problems.
- You have serious stomach or gut problems.

- You have heart 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.
- You have an inactive chronic infection with hepatitis B virus.
- You are taking any medicines known to cause damage to the eyes (e.g. tamoxifen).
- You 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 QUINNEL may cause heart rhythm disorders in some patients.
- You experience palpitations or irregular heartbeat, 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.
- You have salt imbalance in the blood (especially low level of potassium or magnesium).
- You have lactose intolerance.

Serious skin rashes have been reported with the use of hydroxychloroquine. 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 QUINNEL and contact your doctor immediately.

Before treatment with QUINNEL

- Before you take this medicine you should have your eyes examined. This testing should be repeated at least every 12 months whilst taking QUINNEL.
- 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.

- QUINNEL can cause lowering of blood glucose level. Please ask your doctor to inform you of signs and symptoms of low blood glucose levels (hypoglycaemia). A check of the blood glucose level may be necessary.

Children

Small children are particularly sensitive to the toxic effect of 4-aminoquinolines, so QUINNEL should be kept out of the sight and reach of children.

- Taking other medicines

Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription, herbal medicines or natural products.

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

- Some antibiotics used for infections (e.g. azithromycin, clarithromycin, erythromycin, gentamicin, neomycin or tobramycin). Taking azithromycin, clarithromycin, or erythromycin at the same time as QUINNEL may increase the chance of you getting side effects that affect your heart.
- Cimetidine – used to treat heartburn and 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 (e.g. tamoxifen).
- Halofantrine, mefloquine – used to treat malaria.
- Medicines used for heart problems (e.g. amiodarone).
- Moxifloxacin – used to treat infections.
- Medicines used to treat epilepsy.
- Medicines used for psychiatric disorders (e.g. amisulpride, quetiapine, risperidone).
- Medicines for depression (e.g. fluoxetine, paroxetine).

The following medicines can change the way QUINNEL works or QUINNEL may affect the way some of these medicines work:

- Digoxin – used to treat abnormal heart rhythms and heart failure.
- Medicines used to treat diabetes (e.g. insulin and antidiabetic tablets).
- Antacids – used for heartburn or indigestion. You should leave a gap of at least 4 hours between taking these medicines and QUINNEL.
- Rabies vaccine.
- Ciclosporin – used after an organ transplantation to help prevent rejection.
- Praziquantel – to treat worm infections.
- Agalsidase – to treat a rare condition called Fabry's disease.
- Itraconazole – to treat fungal infections.
- Anticoagulant drugs such as clopidogrel.
- Medicines used to treat high cholesterol (e.g. gemfibrozil).
- Ritonavir – used to treat HIV.

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

Pregnancy and lactation

QUINNEL 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 re-assess the need for treatment.

QUINNEL 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 QUINNEL is suitable for you.

How to use QUINNEL

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

- How much to use

Your doctor will work out the dose depending on your body weight. Please consult your doctor for the exact dosage to be taken.

Adults (including the elderly):

- 1 or 2 tablets each day.

- The dose can be reduced from 400 mg daily to 200 mg when there is no further improvement.

Children:

- 1 tablet each day.
- This medicine is only suitable for children whose ideal body weight is more than 31 kg.

It may take several weeks before you notice the benefit of taking QUINNEL.

- When to use it

Use as directed by your doctor or pharmacist. Swallow the tablets whole with a meal or a glass of milk. Do not crush or chew your tablets.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

If you are taking this medicine for skin problems that are sensitive to sunlight, only take QUINNEL during periods of high exposure to light.

- How long to use it

Continue taking your medicine for as long as your doctor tells you.

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 forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Take the medicine pack with you. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdose may include: headache, problems with your eyesight, fall in blood pressure, convulsions (fits), heart

problems leading to uneven heartbeats, followed by sudden severe breathing problems and possibly heart attack.

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

While you are using it

- Things you must do

- Always take your medicine exactly according to the instructions given to you by your doctor or pharmacist.
- Inform all the doctors, dentists and pharmacists treating you that you are taking QUINNEL.
- If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking QUINNEL.
- Tell your doctor immediately if you become pregnant while taking this medicine.
- Your doctor will need to perform some eye tests every few months to check that your eyesight is not changing. In extremely rare cases, QUINNEL has been associated with blindness. This can be avoided by having regular eye tests. It is recommended you wear sunglasses when out in the sun.
- Your doctor will need to perform occasional blood tests to check for any blood reactions.
- Your doctor may monitor your blood glucose levels if you have experienced hypoglycaemia while taking QUINNEL.
- Some people being treated with hydroxychloroquine 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, seek medical advice straight away.

- Things you must not do

- Do not stop taking your medicines unless advised by your doctor.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give this medication to anyone else, even if they have the same condition as you.

- Things to be careful of

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.

Side effects

Like all medicines, QUINNEL can cause side effects although not everybody gets them.

Stop taking QUINNEL 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 the eyelids, lips, face, throat or tongue.

Stop taking QUINNEL 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 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 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's 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.
- 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.
- 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.
- You have frequent infections such as fever, severe chills, sore throat or mouth ulcers.

These could be signs of a blood problem known as 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 anaemia.
 - You feel weak, short of breath, bruise more easily than usual and get infections more easily than usual. These could be symptoms of aplastic anaemia.
 - Weakening of the heart muscle (cardiomyopathy) resulting in difficulty breathing, coughing, high blood pressure, swelling, increased heart rate, low amount of urine.
 - Chest pain and shortness of breath and irregular heartbeat (these could be signs of Torsade de pointes), or fast heartbeat.
 - Low blood glucose levels. 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, feeling nervous or anxious, feeling confused, hallucinations, agitated, feeling elated or overexcited, difficulty sleeping.
- Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:
- Stomach pain
 - Feeling sick (nausea)
 - Skin rashes, itching
 - Vomiting, diarrhoea
 - Loss of appetite
 - Headache
 - Mood swings
 - Changes in the colour of your skin or the inside of your nose or mouth
 - Hair loss or loss of hair colour
 - Nervousness
 - Ringing in the ear (tinnitus)
 - Balance problems (vertigo) or feeling dizzy
 - Liver problems shown by blood tests
 - Psoriasis (red scaly patches on the skin, usually affecting the knees, elbows and scalp)
 - Hearing loss
 - Symptoms of a condition called porphyria which may include stomach pain, being sick, fits, blisters, itching

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed in this leaflet may also occur in some patients.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of QUINNEL

Storage

Store below 30°C.

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

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

QUINNEL is white round biconvex film-coated tablet debossed with “H,200” on one side and plain on the other.

- Ingredients

- Active ingredient
Hydroxychloroquine sulfate 200 mg

- Inactive ingredients

Tablet core: Pregelatinized starch, lactose monohydrate, crospovidone, povidone K-30, sodium lauryl sulfate, talcum, colloidal silicon dioxide, magnesium stearate

Film coating: Hypromellose, polyethylene glycol, talcum, Opadry II 32F 18245 white

- Packing

Blister strip of 10 tablets in packing of 100 tablets per box.

- MAL Number

MAL22116012AZ

Manufacturer

Sriprasit Pharma Co., Ltd.
216 Moo 6, Suanluang, Krathum Baen,
Samut Sakhon 74110, Thailand.

Product Registration Holder

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