Package leaflet: information for the user

Hydroxychloroquinesulfaat DOC 200 mg, filmomhulde tabletten

Hydroxychloroquine sulphate

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 <Product name> is and what it is used for

<*Product name*> contains hydroxychloroquine sulphate that works by reducing inflammation in people with autoimmune diseases (this is where the body's immune system attacks itself by mistake).
This medicine is also used to prevent and treat acute attacks of malaria, an infectious disease caused by the presence of parasites in red blood cells, with symptoms such as high fever, shaking, chills, and extreme sweating.

<*Product name*> *is used in adults for:*
- treatment of chronic inflammation of joints, muscles, tendons or muscle attachment inflammation (rheumatoid arthritis)
- treatment of acute malaria attacks and malaria prevention
- treatment of skin problems and/or joint complaints caused by systemic and discoid lupus erythematosus
- treatment of skin rashes following exposure to the sun (photodermatoses).

<*Product name*> *is used in children for:*
- treatment of juvenile arthritis in combination with other treatments
- treatment of skin problems and/or joint complaints caused by systemic and discoid lupus erythematosus.
- treatment of acute malaria attacks and malaria prevention.

<Product name> does not work against certain types of malaria (chloroquine-resistant).

2. What you need to know before you take <Product name>

Do not take <Product name>
- If you are allergic to hydroxychloroquine, other similar medicines such as quinolones and quinine or any of the other ingredients of this medicine (listed in Section 6).
- If you are suffering from a disease of the eye which makes your vision indistinct or blurred (maculopathy).
- If you are suffering from a form of muscle weakness (myasthenia gravis).
- If you are suffering from a retina disease with pigment formation (retinitis pigmentosa).
- If your body weight is less than 35 kg.

Warnings and precautions

Talk to your doctor before taking <Product name>.
Inform your doctor if any of the following conditions applies to you or has applied in the past:
- Movement disorders (extrapyramidal disorders) may occur (see section 4 “Possible side effects”).
- Vision problems (for example, blurred vision, the sense that your field of vision is deteriorating or that you are seeing less colours). Before starting treatment with this medicine, your doctor will investigate your eyes in order to determine whether there are any problems. This eye exam will need to be repeated in long-term use of this medicine. Concomitant use of medicines that are known to be harmful for the retina, including tamoxifen, is not recommended.
- Porphyria (a rare inherited blood disorder in which people do not properly make the heme, a component of haemoglobin, the protein in red blood cells that carries oxygen). This could get worse by using this medicine. In long-term use, your blood will be checked regularly.
- You have an inactive chronic infection with hepatitis B virus.
- Liver or kidney disorder. Your doctor will monitor you carefully in case you have a deficiency of a certain liver enzyme (glucose-6-phosphate dehydrogenase deficiency).
- Heart rhythm disorders.<Product name> may cause heart rhythm disorders in some patients: caution should be taken when using <Product name>, 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 <Product name>”). 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. Additionally, heart failure has been observed after taking this medicine, which may be fatal in rare cases. Symptoms of heart failure include fatigue, being short of breath and having swollen legs and ankles. Contact your doctor if any of these symptoms occur.
- Hypoglycaemia (low blood sugar levels). This medicine is known to significantly lower blood sugar levels. If you notice signs such as sweating, trembling, dizziness, sudden mood swings, lack of focus, headaches, fatigue, hungriness or loss of consciousness, contact your doctor to check your blood sugar levels.
- If you are using this medicine for a long period, your muscles and tendons will need to be periodically checked. Contact your doctor if you start suffering from weak muscles or tendons, doctor may decide to stop the treatment.
- Some people being treated with <Product name> 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.
- Psoriasis (a skin disease characterised by flaking). Your doctor will carefully monitor you during the use of this medicine. (See section 4 “Possible side effects”).
- 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.
- Tell your doctor if you are hypersensitive to quinine.

Children and adolescents
Children are particularly sensitive to the toxic effect of this medicine, so <Product name> should be kept out of the reach of children.

Other medicines and <Product name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
This includes in particular:
- Concurrent use of hydroxychloroquine with digoxin (heart medication) can lead to an undesirably strong effect of digoxin.
- Monoamine-oxidase (MAO) inhibitors, used as antidepressant. You should not use these medications at the same time.

- Medicines used for depression (fluoxetine, paroxetine).
- Hydroxychloroquine can enhance the blood-sugar reducing effect. Because of this, it could be possible that the dose of insulin or other anti-diabetic medicine needs to be decreased.
- Hydroxychloroquine inhibits an enzyme primarily produced by the liver, named CYP2D6. For this reason, medicines that also inhibit CYP2D6 cannot be used concurrently with hydroxychloroquine.
- Hydroxychloroquine can diminish the effect of the rabies vaccine. It is not advisable to administer the rabies vaccine by subcutaneous injection when using <Product name>. When the vaccine is administered by intramuscular injection, the level of protection is sufficient.
- Hydroxychloroquine can increase sensitivity to epileptic episodes. Concurrent use of hydroxychloroquine and antimalarial drugs that also increase sensitivity (such as mefloquine), may trigger spells of unconsciousness with muscle spasms (convulsions).
- The efficacy of anti-epileptic drugs may be affected if they are used concurrently with hydroxychloroquine.
- Drugs known to affect the rhythm of your heart. This includes medicines used for abnormal heart rhythm (antiarrhythmics), for depression (tricyclic antidepressants), for psychiatric disorders (antipsychotics), for bacterial infections (e.g. moxifloxacin, azithromycin), for HIV treatment (e.g. saquinavir), for fungal infections (e.g. fluconazole), for parasitic infections (e.g. pentamidine) or against malaria (e.g. halofantrine).
- Antacid medicines (for heartburn) and kaolin. Take <Product name> at least 2 hours apart from those.
- Some medicines can interfere with the effect of hydroxychloroquine when taken together. They may increase or decrease the effect of hydroxychloroquine, either leading to increased side effects or making hydroxychloroquine less effective. These include medicines used for stomach ulcers (cimetidine), for fungal infections (such as itraconazole), for bacterial infections (such as rifampicin, clarithromycin), for epilepsy (seizures) (such as phenobarbital, phenytoin, carbamazepine), for lipid disorders (such as gemfibrozil, statins), for HIV treatment (such as ritonavir) (the cause of AIDS is the HIV virus), for organ transplants or diseases of the immune system (such as ciclosporin), for blood clots (such as dabigatran, clopidogrel), for heart diseases (such as digoxin, flecainide, propafenone, quinidine and metoprolol) and a herbal treatment for depression: St. John's wort.

<Product name> with food
Avoid taking grapefruit juice, as it may increase the risk of side effects.

Pregnancy, 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.

Pregnancy
<Product name> 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.
This medicine can be used during pregnancy to prevent malaria since only low doses are required.
Breast-feeding
Hydroxychloroquine is excreted in breast milk. There is insufficient information on the effects of <Product name> in newborns/infants. When using this medicine in high doses for long time, you should stop breast-feeding.
When taking this medicine to prevent malaria, you do not need to quit breast-feeding. This amount is not enough to prevent malaria in your child by the suckling.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breastfeeding. Your doctor will discuss with you whether <product name> is suitable for you.

Fertility
There is no information about the effects of <Product name> on fertility in humans.

Driving and using machines
<Product name> can cause blurred vision and dizziness. If you experience any of these side effects, you should not drive a car or operate any machine.

3. How to take <Product name>
Always take this medicine exactly as your doctor or pharmacist has told you. It is important that you do this as long as your doctor or pharmacist tells you to. Check with your doctor or pharmacist if you are not sure.

It is preferable to take <Product name> tablets after a meal.

How much <Product name> to take
The recommended dose in adults is:

• *If you are being treated for rheumatoid arthritis*
Starting dose: 400 mg a day
Maintenance dose: 200 mg a day and later, if possible 200 mg every other day.

• *If you are being treated for systemic and discoid lupus erythematosus*
Starting dose: 400 mg to 600 mg a day
Maintenance dose: 200 mg to 400 mg a day

• *If you are being treated for photodermatosis (skin rashes following exposure to the sun)*
The treatment is limited to periods in which you are exposed to sunlight.
For adults: 400 mg a day is usually enough

• *If you are being treated for prophylaxis of malaria*
Adults: 400 mg a week on the same day every week.
In order to prevent malaria, the treatment needs to be started one week before arrival in an area with malaria and needs to be continued about four to eight weeks after leaving said area.

• *If you are being treated for treatment of an acute malaria attack*
The dose for an acute attack of malaria depends on the nature of the infection.
The total dose is maximum 2 grams and needs to be administered over a maximum period of three days.

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

Use in people with impaired renal and liver function
If you have impaired renal or liver function, your doctor can prescribe you a lower dose.

How long to take <Product name>
Follow your doctor's instructions regarding the duration of the treatment. For a long-term treatment, your doctor will prescribe you the lowest possible dose.
For the treatment of joint inflammation, this medicine needs a few weeks in order to reach the best possible effect.

If you take more <Product name> than you should
If you accidentally take more <Product name> than you should, tell a doctor straight away. Take the medicine pack with you.
An overdose is dangerous, especially for young children.
If you have taken more than the prescribed dose, the following effects may happen: headaches, blurred vision, fainting (by impaired heart functions), heart problems leading to uneven heart beats and fits, followed by suddenly occurring interruption in breathing and cardiac arrest, which may be fatal. Immediately contact your doctor if any of these symptoms occur.

If you forget to take <Product name>

- 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.
- Then continue with your normal schedule.
- Do not take a double dose to make up for a forgotten dose.
- If you have missed more than one dose, please contact your doctor or pharmacist.

If you stop taking <Product name>

Keep taking <Product name> until your doctor tells you to stop.

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 everybody gets them.

Stop taking [product name] 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 (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 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.

Side effects can occur in the following frequencies:

Common (may affect up to 1 in 10 people)
- Diminished appetite (anorexia).
- Feeling emotional.

Uncommon (may affect up to 1 in 100 people)
- Nausea, diarrhoea and abdominal pain. These symptoms usually disappear after lowering the dose or stopping the treatment.
- Skin rash.
- Nervousness.

Rare (may affect up to 1 in 1,000 people)
- Decrease in production of blood cells (diminished bone marrow function).
- Fits/seizures (convulsions).
- Retinal changes. Sometimes you may barely notice this in the beginning, but you may also develop spots or circles in your vision, have altered colour perception or notice that some parts of your field of vision are not visible.
  If you notice these problems early, they will usually decrease after stopping the treatment with <Product

name>.
Should you only notice these changes late, the problems could persist after stopping the treatment and may worsen.
- Macular degeneration has been observed and may be irreversible.
- Vomiting. This usually disappears after lowering the dose or stopping the treatment.
- Cardiac muscle disease (cardiomyopathy) which may be fatal in case of high-dose long-term use, (see section 2 “Warning and precautions”).

Very rare (may affect up to 1 in 10,000 people)
- Loss of hearing (permanent).
- Erythema multiforme (redness of the skin with (moist) irregular spots).
- Severe hypersensitivity reaction that can occur with high fever, red spots on the skin, joint pains and/or eye infection (Stevens - Johnson syndrome).
- Severe, sudden (oversensitivity) reaction accompanied by fever and blisters on the skin and skin shedding (toxic epidermal necrolysis).
- Certain form of sudden skin rash with acne (acute generalised exanthematous pustulosis (AGEP) which may include fever and an increase in the number of white blood cells (hyperleukocytosis).

Not known (frequency cannot be estimated from the available data)
- Anaemia and aplastic anaemia.
- Very severe blood disorders (white blood cells deficiency), with sudden high fever, serious throat pain and mouth ulcers (agranulocytosis).
- Decrease in white blood cells (leukopenia).
- Blood disorder (blood platelets deficiency) accompanied by bruises and bleeding (thrombocytopenia).
- Worsening of a red blood pigment disorder (porphyria).
- Dizziness/vertigo.
- Psychosis (an abnormal condition of the mind that involves a "loss of contact with reality". People may exhibit personality changes and thought disorder, which may be accompanied by unusual or bizarre behavior, difficulty with social interaction and impairment in carrying out daily life activities).
- Feeling depressed or having thoughts of self-harm or suicide, hallucinations, feeling nervous or anxious, feeling confused, agitated, difficulty sleeping, feeling elated or overexcited.
- Ear-ringing (tinnitus).
- Headache.
- Retinal changes, field of vision disorders, in which parts of the field of vision are invisible, temporary blind spots in the field of vision (scotoma) and deviated colour perception.
- Corneal changes, including accumulation of liquids (oedema) and lack of transparency (opacity).
- Blurred vision due to impaired ability of the eye to accomodate. This problem is temporary and decreases when the dose is lowered.
- Conductivity disorders in the hearth. Abnormal heart rhythm, life-threatening irregular heart rhythm (seen on ECG) (see section 2 “Warning and precautions”).
- Enlargement of both heart chambers (biventricular hypertrophy).
- Blood sugar lowering (hypoglycaemia).
- Very severe liver disorder (fulminant hepatic failure).
- Abnormal liver test results.
- Itching, change in the colour of skin, mucous membranes or hair lightening and hair loss (alopecia) (these symptoms usually vanish after lowering the dose of terminating the treatment).
- Oversensitivity to light (photosensitivity).
- Skin rash with redness and flaking (exfoliative dermatitis).
- Reoccurring skin condition accompanied by flaking, dry skin rash (psoriasis).
- A rare oversensitivity reaction (DRESS syndrome), characterised by fever, skin rash and an increased amount of white blood cells accompanied by hepatic and lung disorders.
- Muscle afflictions, which also affect the nerves and lead to weakness (myopathy and neuromyopathy leading to progressive weakness).
- Decrease in muscle tissue leading to a reduction of muscle strength (atrophy).

- Movement problems (extrapyramidal disorders) such as stiffness (dystonia), abnormal movements (dyskinesia) or shaking (tremor) of the body muscles (see also "Warnings and precautions").
- Changes in sensory perceptions.
- Diminished tendon reflex.
- Problems shown by test for nerve conduction.
- Allergic reactions such as skin rash with heavy itching or lump formation (gall lumps or urticaria) and swelling of the skin or mucous membranes with itch (angio-oedema).
- Short breath due to cramps in the muscles of the respiratory passages (bronchospasms).

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 national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store <Product name>
- 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 and carton after 'EXP'. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.
- 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 <Product name> contains
- The active substance is hydroxychloroquine sulphate. Each tablet contains 200 mg of hydroxychloroquine sulphate.
- The other ingredients are:
  Tablet core: maize starch, calcium hydrogen phosphate dihydrate (E341), silica colloidal anhydrous (E551), polysorbate 80 (E433), dried maize starch, talc (E553b) and magnesium stearate (E470b)
  Film coating: hypromellose (E464), talc (E553b), titanium dioxide (E171) and macrogol 6000.

What <Product name> looks like and content of the pack
<Product name> are white, round, biconvex film-coated tablets (with a dimension of 9.5 mm) embossed with "200" on one side and plain on other side.

This medicine is available in blister pack containing 30 tablets.

Vergunninghouder:
DOC Generici S.r.l. - Via Filippo Turati 40, Milaan 20121 – Italië.

Fabrikant:
PharmaS d.o.o. - Industrijska cesta 5, Potok, 44317 Popovaca - Kroatië

In het register ingeschreven onder:
RVG 122221

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland: Hydroxychloroquinesulfaat DOC 200 mg, filmomhulde tabletten
Italië: IDROSSICLOROCHINA DOC

Deze bijsluiter is voor het laatst goedgekeurd in januari 2024.