

PART II: CONSUMER INFORMATION

PrPRO-QUININE – 200

PrPRO-QUININE – 300

Quinine Sulfate Capsules

200 mg and 300 mg

Manufacturer Standard

This leaflet is Part II to complement the Prescribing Information (Part I) for PRO-QUININE. Part I is designed for health care practitioner and Part II is designed specifically for patients / consumers. This leaflet is a summary and will not tell you everything about PRO-QUININE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

PRO-QUININE is used orally in combination with a second antimalarial drug for the treatment of uncomplicated Plasmodium falciparum malaria, as determined by the doctor.

What it does:

The exact mechanism of PRO-QUININE action has not been determined but it is believed to concentrate in the parasite, disrupt the transport of key biological substances and activities, thereby killing the parasite.

When it should not be used:

PRO-QUININE should not be used if you:

- have a known hypersensitivity (allergic reaction) to quinine, quinidine, mefloquine or the non-medicinal ingredients in the formulation (e.g. list of non-medicinal ingredients).

Hypersensitivity reactions may include:

- thrombocytopenia (decreased blood platelets) and related conditions
- hemolytic uremic syndrome (disease with acute kidney failure, low blood platelet count and hemolytic anemia (early destruction of red blood cells))
- blackwater fever (complication of malaria when the red blood cells burst in the bloodstream with symptoms such as chills, fever, jaundice, vomiting, dark red or black urine)
- have heart rhythm problems (e.g. QT interval prolongation)
- have myasthenia gravis (autoimmune disease with muscle weakness)
- have low levels of glucose-6-phosphate dehydrogenase (G-6-PD), a certain enzyme
- have optic neuritis (inflammation of the eye)
- have hypoglycemia (low blood sugar)

What the medicinal ingredient is:

Quinine sulfate

What the non-medicinal ingredients are:

The non-medicinal ingredients are: colloidal silicon dioxide, gelatin, lactose monohydrate, magnesium stearate, pregelatinized starch, purified water, sodium lauryl sulfate and talc. Black ink: ammonium hydroxide, black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water and shellac.

What dosage forms it comes in:

200 mg and 300 mg Capsules

WARNINGS AND PRECAUTIONS

Talk to your doctor about all the drugs you are taking before taking PRO-QUININE (see Interactions with this medicine).

BEFORE you use PRO-QUININE talk to your doctor or pharmacist if:

- You have heart rhythm problems such as irregular or fast heartbeat, QT prolongation.
- You have kidney, liver problems or other medical conditions.
- Are pregnant or planning to become pregnant. Treatment of malaria is important as this can be a serious disease for a pregnant woman and her unborn baby. Discuss with your doctor.
- You are breastfeeding. Small amounts of PRO-QUININE can pass into breast milk. Discuss with your doctor.
- Tell your doctor all the medications that you take, including prescription and non-prescription drugs, natural health products, vitamins and herbs (see Interactions with this medication).

Talk to your doctor if the following occurs while taking PRO-QUININE:

- You develop low blood sugar with symptoms such as weakness, dizziness, fatigue, etc.
- You develop a hypersensitivity (allergic) reaction with symptoms such as difficulty breathing, swelling of mouth, throat and extremities, serious skin rash, blistering or peeling skin, itching and other skin reactions. Discontinue PRO-QUININE and see a health care practitioner immediately.
- You develop thrombocytopenia (decrease in blood platelets), or other blood (hematologic) conditions with symptoms such as bleeding in the nose, gums, urine or stool, easy bruising, unusual purple, brown or red spots on the skin. Discontinue PRO-QUININE and contact your health care practitioner immediately.
- You develop heart rhythm irregularities with symptoms such as rapid or irregular rhythm, chest pain, weakness, sweating. Discontinue PRO-QUININE and contact your health care practitioner immediately.
- You develop vision problems including sudden blindness, sensitivity to light, appearance of “floaters” in the eye, eye inflammation (optic neuritis), night blindness. Contact your health care practitioner immediately.
- If your fever comes back after finishing treatment, contact your health care practitioner immediately.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with PRO-QUININE include:

- antacids containing aluminum or magnesium
- anticoagulants (e.g. warfarin)
- antiepileptics (e.g. carbamazepine, phenobarbital, phenytoin)
- digoxin
- inhibitors of CYP 3A4 enzyme such as cyclosporine, antifungal agents (e.g. ketoconazole, itraconazole), macrolide antibiotics (e.g. erythromycin, clarithromycin), HIV protease inhibitors (e.g. ritonavir) and antidepressants (e.g. nefazodone)
- mefloquine (antimalarial)
- neuromuscular blocking agents (e.g. pancuronium, tubocurarine, succinyl chloride)
- quinidine, astemizole*, cisapride*, terfenadine*, halofantrine
- urinary alkalizers (e.g. sodium bicarbonate, acetazolamide)
- HMG-CoA reductase inhibitors (“statins”) to reduce serum cholesterol (e.g. atorvastatin, simvastatin, lovastatin...)

* no longer marketed in Canada

PROPER USE OF THIS MEDICATION

Usual dose:

As directed by a doctor:

For uncomplicated *P. falciparum* malaria: PRO-QUININE will likely be taken with an appropriate antibiotic chosen by the doctor (e.g. tetracycline, doxycycline or clindamycin)

- a) Adults (16 years of age and older): Quinine sulfate 600 mg, every 8 hours after meals for 3-7 days.
- b) Children (less than 16 years): Quinine sulfate 9 mg/kg to a maximum of 600 mg, every 8 hours after meals for 3-7 days. The pharmacist will prepare the children’s dosage from the capsules.

Finish all PRO-QUININE that is prescribed even though you feel better. Do not stop taking the medication without talking to your doctor.

Your doctor may adjust the dosage if you have kidney problems.

If using antacids, take them 2 hours before or 2 hours after PRO-QUININE.

Your doctor/pharmacist will provide instructions on how to use the antibiotic(s).

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Symptoms of overdose may include headache, confusion, blurred vision, irregular or fast heartbeat, vomiting, abdominal pain, breathing difficulties, low blood pressure, coma, and convulsions.

Missed Dose:

If a dose of this medication has been missed, it should be taken as soon as possible. However, if more than 4 hours have passed since the missed dose, skip the missed dose and go back to the regular dosing schedule. Do not double doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Common side effects include ringing in the ears, headache, impaired hearing, nausea, blurred vision, sweating, flushing and dizziness.

Other side effects include vomiting, stomach pain, flushed skin, fever, sweating, diarrhea, deafness, blindness, disturbances in colour perception, heart rhythm irregularities and low blood pressure.

Quinine can affect the retina and optic nerve to cause symptoms such as photophobia (aversion to light), night blindness, altered colour perception and may not be reversible. Contact your doctor if these symptoms appear.

Low blood sugar (hypoglycemia) has also been reported with quinine use with symptoms such as weakness, dizziness, sweating.

Tell your health care practitioner if you have any side effect that bothers you or does not go away.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
Blood disorders with symptoms such as bleeding in nose, gums, stool, easy bruising, red/purple or brown spots on the skin, fatigue, weakness			✓
Heart rhythm irregularities with symptoms such as fast or irregular heartbeat, chest pain, weakness, sweating, etc.			✓
Hypersensitivity (allergic reaction) with symptoms such as difficult breathing, swelling of mouth, throat, rash, serious			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
skin reactions including blistering and peeling skin, etc.			
Vision abnormalities such as sensitivity to light, night blindness, sudden blindness, appearance of “floaters”, eye inflammation, altered colour perception			✓

This is not a complete list of side effects. For any unexpected effects while taking PRO-QUININE, contact your doctor or pharmacist.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

HOW TO STORE IT

Store at room temperature 15 to 30°C.

Keep out of reach and sight of children.

If you want more information about PRO-QUININE

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://www.hc-sc.gc.ca/>); or by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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