

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

Pr**PRIMAQUINE**[®]

Primaquine phosphate tablets USP

Read this carefully before you start taking **PRIMAQUINE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PRIMAQUINE**.

What is PRIMAQUINE used for?

PRIMAQUINE is used to:

- treat certain forms of malaria, and
- help prevent it from coming back.

How does PRIMAQUINE work?

PRIMAQUINE is a type of drug called an antimalarial.

- It is used to treat malaria by killing the parasite in the liver that causes malaria.
- This stops the infection from continuing.

What are the ingredients in PRIMAQUINE?

Medicinal ingredients: primaquine phosphate

Non-medicinal ingredients: carnauba wax, cellulose (microcrystalline), lactose, magnesium stearate, Opacode Black ink S-1-177003 (contains shellac glaze; propylene glycol; N-butyl alcohol; black iron oxide; ethanol and methanol), Opadry white YS-1-7443 (contains hypromellose; polyethylene glycol 400; titanium dioxide; and polysorbate 80), polyethylene glycol 400, red iron oxide, starch and talc. *Gluten and tartrazine-free.*

PRIMAQUINE comes in the following dosage forms:

Tablets: 26.3 mg primaquine phosphate (equivalent to 15 mg primaquine base)

Do not use PRIMAQUINE if:

- You are allergic to:
 - primaquine phosphate, or
 - any of the ingredients in the product (see **What are the ingredients in PRIMAQUINE**).
- You have a disease where you lack white blood cells. Examples include rheumatoid arthritis or lupus erythematosus. You should not take **PRIMAQUINE** if you are very sick with a systemic disease.
- You are taking or have recently taken quinacrine. Quinacrine is another medicine used to treat malaria.
- You are taking medicines that can:

- damage your blood cells, or
 - impair the formation of new blood cells.
- You have a disease called severe G6PD (glucose-6-phosphate dehydrogenase) deficiency. This is a hereditary red blood cell disease, also known as favism.
- You are pregnant, could be pregnant, or are planning to become pregnant. You must NOT become pregnant while taking PRIMAQUINE or for **2 menstrual cycles** after stopping.
 - You must use reliable birth control to make sure you don't get pregnant while you are taking PRIMAQUINE and for 2 menstrual cycles after stopping.
- You are male and planning to father a child. You must NOT father a child while taking PRIMAQUINE or for **3 months** after stopping.
 - You must use reliable birth control to make sure you don't father a child while you are taking PRIMAQUINE and for 3 months after stopping.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRIMAQUINE. Talk about any health conditions or problems you may have, including if you:

- Have, or have a family history of, G6PD deficiency (also known as favism). PRIMAQUINE must not be used if you have severe G6PD deficiency.
- Have a rare blood disease called nicotinamide adenine dinucleotide (NADH) methemoglobin reductase deficiency.
- Have anemia. This is a lower than normal level of red blood cells.
- Have hemolytic anemia. This is a condition where your red blood cells are destroyed before their normal lifespan is over.
- Have a liver or kidney disease.
- Are above 65 years old.
- Are breastfeeding or planning to breastfeed. Breastfeeding should be stopped while you are taking PRIMAQUINE, or treatment with PRIMAQUINE should be delayed until the end of breastfeeding. You should NOT breastfeed while taking PRIMAQUINE.
- Have or have had:
 - heart disease
 - an irregular heartbeat
 - low levels of magnesium or potassium in your blood
 - a resting heart rate below 50 beats per minutes

Other warnings you should know about:

Before your start taking PRIMAQUINE, your healthcare professional will do a blood test to see if you have G6PD deficiency. This is because PRIMAQUINE can cause the destruction of red blood cells (hemolysis) in people with G6PD deficiency. Based on the results of this test, your healthcare professional may need to change your treatment.

Before and during your treatment, your healthcare professional may ask for blood tests to make sure there is no trouble with your red blood cells.

Stop taking PRIMAQUINE right away and contact your healthcare professional if you have: darkening of the urine, pale skin, dizziness, confusion, fatigue, light-headedness, shortness of breath. These are signs of hemolytic anemia.

Contact your healthcare professional right away if you have bluish lips or nails. These are signs of damage to your red blood cells (methemoglobinemia).

Driving or Using Machines: PRIMAQUINE may cause dizziness. Do not drive or operate machinery until you know how PRIMAQUINE affects you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with PRIMAQUINE:

- quinacrine. PRIMAQUINE must not be used together with quinacrine.
- medicines that can destroy or damage red blood cells or impair formation of red or white blood cells such as: some anti-infectives (sulfamides, dapsone, cotrimoxazole, quinolones), medicines used to treat cancer, colchicine, methylene blue, penicillamine, gold salts. PRIMAQUINE should not be used together with these medicines.
- medicines known to affect the way your heart beats:
 - this includes medicines used for abnormal heart rhythm:
 - antiarrhythmics such as:
 - quinidine
 - hydroquinidine
 - disopyramide
 - sotalol
 - dofetilide
 - ibutilide
 - amiodarone
 - medicines used to treat depression:
 - tricyclic antidepressants such as:
 - amitriptyline
 - imipramine
 - medicines used to treat mental health problems: antipsychotics
 - medicines used to treat bacterial infections:
 - macrolide antibiotics such as:
 - erythromycin
 - fluoroquinolone antibiotics such as:
 - moxifloxacin
 - medicines used to treat malaria (in particular halofantrine),
 - medicines used to treat other infections: pentamidine.
 - medicines used to treat depression, known as selective serotonin reuptake inhibitors (SSRIs), such as fluoxetine or paroxetine.
 - digoxin (for heart disease), dabigatran (to prevent blood clots), theophylline (for respiratory disorders), alosetron (for vomiting) and tizanidine (for nerve disorders).

How to take PRIMAQUINE:

Taking PRIMAQUINE after a meal may help to decrease stomach pain or cramps.

Usual dose:

Take PRIMAQUINE exactly as prescribed by your healthcare professional. You should check with your healthcare professional if you are not sure. To make sure your treatment works, you should take your medicine for as long as your healthcare professional tells you to.

Overdose:

If you think you have taken too much PRIMAQUINE, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Symptoms that you have taken too much PRIMAQUINE include: stomach cramps, vomiting, yellowing of the skin and the whites of the eyes, heartburn, heart problems, including problems with your heartbeat rhythm, bluish skin discoloration, fatigue, difficulty breathing, shortness of breath, confusion, light-headedness, dizziness, difficulty sleeping, pale skin.

Missed Dose:

If you miss a dose of PRIMAQUINE, take it as soon as possible. However, if it is time for your next dose, do not take a double dose. Just carry on with your regular schedule, until you are finished taking all your pills.

What are possible side effects from using PRIMAQUINE?

These are not all the possible side effects you may feel when taking PRIMAQUINE. If you experience any side effects not listed here, contact your healthcare professional. Please also see **Other warnings you should know about** section.

Side effects may include: nausea, vomiting, itching, stomach cramps, anemia (low red blood cells), heartburn, rash, dizziness, low white blood cells.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Hemolytic anemia (low red blood cells due to their destruction): darkening of the urine, pale skin, shortness of breath, dizziness and fatigue			X
Methemoglobinemia (damage of red blood cells): bluish lips or nails		X	
Abnormal heartbeat rhythm: irregular heartbeat		X	

If you have a troublesome symptom or side effect that is not listed here, or one that becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

Storage:

Store between 15-30°C.

Keep out of reach and sight of children.

If you want more information about PRIMAQUINE:

- 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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.sanofi.ca, or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

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