

PRESCRIBING INFORMATION

Including Patient Medication Information

PrTEVA-CHLOROQUINE
(Chloroquine Phosphate)
Tablets

250 mg

USP

Antimalarial – Antiparasitic

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PrTEVA-CHLOROQUINE
(Chloroquine Phosphate Tablets)
250 mg

THERAPEUTIC CLASSIFICATION

Antimalarial – Antiparasitic

ACTION AND CLINICAL PHARMACOLOGY

Chloroquine has been found to be highly active against the asexual erythrocytic forms of *Plasmodium vivax*, *ovale* and *malariae* and many strains of *Plasmodium falciparum* (but not the gametocytes of *Plasmodium falciparum*). The precise mechanism of plasmodicidal action of the drug is not known. Chloroquine may exert its effect against *Plasmodium* species by concentrating in the acid vesicles of the parasite and by inhibiting polymerization of heme. While the drug can inhibit certain enzymes, its effect is believed to result, at least in part, from its interaction with DNA.

Chloroquine does not prevent infection but acts on the erythrocytic form of the parasite, inhibiting parasite development in the red cell thus preventing or suppressing clinical symptoms. Chloroquine does not prevent relapses in patients with *vivax* or *ovale* malaria because it is not effective against exo-erythrocytic forms of the disease. It is highly effective as a suppressive agent in patients with *vivax* or *ovale* malaria, in terminating acute attacks, and significantly lengthening the interval between treatment and relapse. In patients with *falciparum* malaria, it abolishes the acute attack and effects complete cure of the infection, unless due to a resistant strain of *P. falciparum*.

In vitro studies with trophozoites of *Entamoeba histolytica* have demonstrated that chloroquine also possesses amebicidal activity comparable to that of emetine.

Resistance of *Plasmodium* parasites to chloroquine is widespread (see INDICATIONS AND CLINICAL USE, Limitations of Use in Malaria and PRECAUTIONS).

Plasmodium parasites exhibiting reduced susceptibility to hydroxychloroquine also show reduced susceptibility to chloroquine.

Patients in whom chloroquine or hydroxychloroquine have failed to prevent or cure clinical malaria or parasitemia, or patients who acquired malaria in a geographic area where chloroquine resistance is known to occur should be treated with another form of antimalarial therapy (see PRECAUTIONS and INDICATIONS AND CLINICAL USE, Limitations of Use).

Chloroquine is rapidly and almost completely absorbed from the gastrointestinal tract, with only a small proportion of the administered dose found in the stools. Approximately 55% of the drug in the plasma is bound to nondiffusible plasma constituents. Chloroquine is deposited in tissues in considerable amounts. In animals, from 200 to 700 times the plasma concentration may be found in the liver, spleen, kidney and lung; leukocytes also concentrate the drug. The brain and spinal cord, in contrast, contain only 10 to 30 times the amount present in plasma.

Chloroquine undergoes appreciable degradation in the body. The main metabolite is desethylchloroquine, which accounts for one fourth of the total material appearing in the urine; bisdesethylchloroquine, a carboxylic acid derivative, and other uncharacterized metabolites are found in small amounts. Slightly more than half of the urinary drug products can be accounted for as unchanged chloroquine. Excretion is quite slow, but can be increased by acidification of urine.

INDICATIONS AND CLINICAL USE

TEVA-CHLOROQUINE (chloroquine phosphate) is indicated for the suppressive treatment of malaria and for the curative treatment of acute attacks of malaria due to *P. vivax*, *P. malariae*, *P. ovale*, and susceptible strains of *P. falciparum*.

TEVA-CHLOROQUINE is also indicated for treatment of extraintestinal amebiasis.

Limitations of use in malaria:

- Do not use chloroquine phosphate tablets for the treatment of complicated malaria (high-grade parasitemia and/or complications e.g., cerebral malaria or acute renal failure).
- Do not use chloroquine phosphate tablets for malaria prophylaxis in areas where chloroquine resistance occurs. Resistance to chloroquine phosphate is widespread in *P. falciparum*, and is reported in *P. vivax* (see PRECAUTIONS).
- Concomitant therapy with an 8-aminoquinoline drug is necessary for treatment of the hypnozoite liver stage forms of *P. vivax* and *P. ovale* (see DOSAGE AND ADMINISTRATION).

CONTRAINDICATIONS

TEVA-CHLOROQUINE (chloroquine phosphate) is contraindicated in the presence of retinal or visual field changes either attributable to 4-aminoquinoline compounds or to any other etiology, and in patients with known hypersensitivity to 4-aminoquinoline compounds.

PRECAUTIONS

Chloroquine-resistant malaria

In recent years it has been found that certain strains of *P. falciparum* have become resistant to 4-aminoquinoline compounds (including chloroquine and hydroxychloroquine) as shown by the fact that normally adequate doses have failed to prevent or cure clinical malaria or parasitemia. Treatment with quinine or other specific forms of therapy is therefore advised for patients infected with a resistant strain of parasites.

Chloroquine phosphate is not effective against chloroquine- or hydroxychloroquine-resistant strains of Plasmodium species (see ACTION AND CLINICAL PHARMACOLOGY). Chloroquine resistance is widespread in *P. falciparum* and is reported in *P. vivax*. Before using chloroquine for prophylaxis, it should be ascertained whether chloroquine is appropriate for use in the region to be visited by the traveler. Information regarding the geographic areas where resistance to chloroquine occurs is available at the Committee to Advise on Tropical Medicine and Travel (CATMAT) (<https://www.canada.ca/en/public-health/services/catmat.html>).

Patients infected with a resistant strain of plasmodia as shown by the fact that normally adequate doses have failed to prevent or cure clinical malaria or parasitemia should be treated with another form of antimalarial therapy.

Retinopathy

Irreversible retinal damage has been observed in some patients who had received long-term or high dosage 4-aminoquinoline therapy. Retinopathy has been reported to be dose related.

When prolonged therapy with any antimalarial compound is contemplated, initial (baseline) and periodic ophthalmologic examinations (including visual acuity, expert slit lamp, funduscopy, and visual field tests) should be performed.

If there is any indication (past or present) of abnormality in the visual acuity, visual field, or retinal macular areas (such as pigmentary changes, loss of foveal reflex), or any visual symptoms (such as light flashes and streaks) which are not fully explainable by difficulties of accommodation or corneal opacities TEVA-CHLOROQUINE (chloroquine phosphate) should be discontinued immediately and the patient closely observed for possible progression. Retinal changes (and visual disturbances) may progress even after cessation of therapy.

A baseline ophthalmological examination should be performed within the first year of starting chloroquine phosphate. The baseline exams should include best corrected distance visual acuity (BCVA), an automated threshold visual field (VF) of the central 10

degrees (with retesting if an abnormality is noted), and spectral domain optical coherence tomography (SD-OCT).

For individuals with significant risk factors (daily dose of chloroquine phosphate greater than 2.3 mg/kg of actual body weight, subnormal glomerular filtration, use of tamoxifen citrate or concurrent macular disease) monitoring should include annual examinations which include BCVA, VF and SD-OCT. For individuals without significant risk factors, annual exams (including BCVA, VF and SD-OCT) can usually be deferred until five years of treatment.

In individuals of Asian descent, retinal toxicity may first be noticed outside the macula. In patients of Asian descent, it is recommended that visual field testing be performed in the central 24 degrees instead of the central 10 degrees.

Auditory effects

In patients with preexisting auditory damage, chloroquine should be administered with caution. In case of any defects in hearing, chloroquine should be immediately discontinued, and the patient closely observed (see ADVERSE EFFECTS).

Muscular weakness

All patients on long-term therapy with TEVA-CHLOROQUINE should be questioned and examined periodically, including testing knee and ankle reflexes, to detect any evidence of muscular weakness. If weakness occurs, discontinue the drug.

Pediatric accidental ingestion

A number of fatalities have been reported following the accidental ingestion of chloroquine, sometimes in relatively small doses (750 mg or 1 g chloroquine phosphate in one 3 year old child). Patients should be strongly warned to keep this drug out of the reach of children because they are especially sensitive to the 4-aminoquinoline compounds.

Worsening of psoriasis and porphyria

Use of TEVA-CHLOROQUINE in patients with psoriasis may precipitate a severe attack of psoriasis. When used in patients with porphyria the condition may be exacerbated. The drug should not be used in these conditions unless in the judgment of the physician the benefit to the patient outweighs the possible hazard.

Pregnancy

Usage of this drug during pregnancy should be avoided except in the suppression or treatment of malaria when in the judgment of the physician the benefit outweighs the possible hazard. It should be noted that radioactively tagged chloroquine administered i.v.

to pregnant pigmented CBA mice passed rapidly across the placenta, accumulated selectively in the melanin structures of the fetal eyes and was retained in the ocular tissues for 5 months after the drug had been eliminated from the rest of the body.

Lactation

Chloroquine is excreted in human breast milk.

Use in patients with hepatic impairment

Since the drug is known to concentrate in the liver, it should be used with caution in patients with hepatic disease or alcoholism or in conjunction with known hepatotoxic drugs.

Hematological effects/laboratory tests

Complete blood cell counts should be made periodically if patients are given prolonged therapy. If any severe blood disorder appears which is not attributable to the disease under treatment, discontinuance of the drug should be considered. TEVA-CHLOROQUINE should be administered with caution to patients having G-6-PD (glucose-6-phosphate dehydrogenase) deficiency.

Cardiac Effects

Cases of cardiomyopathy resulting in cardiac failure, in some cases with fatal outcome, have been reported in patients treated during long term therapy at high doses with chloroquine (see ADVERSE EFFECTS and SYMPTOMS AND TREATMENT OF OVERDOSE). Monitor for signs and symptoms of cardiomyopathy and discontinue chloroquine if cardiomyopathy develops. Chronic toxicity should be considered when conduction disorders (bundle branch block / atrio-ventricular heart block) are diagnosed. If cardiotoxicity is suspected, prompt discontinuation of chloroquine may prevent life-threatening complications. QT interval prolongation, torsades de pointes, and ventricular arrhythmias have been reported. The risk is greater if chloroquine is administered at high doses. Fatal cases have been reported. Chloroquine should be used with caution in patients with cardiac disease, a history of ventricular arrhythmias, uncorrected hypokalemia and/or hypomagnesemia, or bradycardia (<50 bpm), and during concomitant administration with QT interval prolonging agents due to potential for QT interval prolongation (see PRECAUTIONS, Drug Interactions, ADVERSE EFFECTS and SYMPTOMS AND TREATMENT OF OVERDOSE)

Drug interactions

Antacids and kaolin: Antacids and kaolin can reduce absorption of chloroquine; an interval of at least 4 hours between intake of these agents and chloroquine should be observed.

Cimetidine: Cimetidine can inhibit the metabolism of chloroquine, increasing its plasma level. Concomitant use of cimetidine should be avoided.

Insulin and other antidiabetic drugs: As chloroquine may enhance the effects of a hypoglycemic treatment, a decrease in doses of insulin or other antidiabetic drugs may be required.

Arrhythmogenic drugs: There may be an increased risk of inducing ventricular arrhythmias if chloroquine is used concomitantly with other arrhythmogenic drugs, such as amiodarone or moxifloxacin.

Ampicillin: In a study of healthy volunteers, chloroquine significantly reduced the bioavailability of ampicillin. An interval of at least two hours between intake of ampicillin and chloroquine should be observed.

Cyclosporine: After introduction of chloroquine (oral form), a sudden increase in serum cyclosporine level has been reported. Therefore, close monitoring of serum cyclosporine level is recommended and, if necessary, chloroquine should be discontinued.

Mefloquine: Co-administration of chloroquine and mefloquine may increase the risk of convulsions.

Praziquantel: In a single-dose interaction study, chloroquine has been reported to reduce the bioavailability of praziquantel.

Tamoxifen: Concomitant use of chloroquine with drugs known to induce retinal toxicity such as tamoxifen is not recommended.

Hypoglycemia

Chloroquine has been shown to cause severe hypoglycemia including loss of consciousness that could be life-threatening in patients treated with or without antidiabetic medications (see PRECAUTIONS, Drug interactions). Patients treated with chloroquine phosphate should be warned about the risk of hypoglycemia and the associated clinical signs and symptoms. Patients presenting with clinical symptoms suggestive of hypoglycemia during treatment with chloroquine should have their blood glucose level checked and treatment reviewed as necessary.

ADVERSE EFFECTS

Ocular: irreversible retinal damage in patients receiving long-term or high-dosage 4-aminoquinoline therapy; visual disturbances (blurring of vision and difficulty of focusing or accommodation); nyctalopia; scotomatous vision with field defects of paracentral, pericentral ring types, and typically temporal scotomas, e.g., difficulty in reading with words tending to disappear, seeing half an object, misty vision and fog before the eyes.

Neuromuscular: convulsive seizures.

Auditory: nerve type deafness; tinnitus, reduced hearing in patients with preexisting auditory damage.

Gastrointestinal: anorexia, nausea, vomiting, diarrhea, abdominal cramps.

Dermatologic: pleomorphic skin eruptions, skin and mucosal pigmentary changes; lichen planus-like eruptions, pruritus and hair loss.

Central nervous system: mild and transient headache, psychic stimulation, polyneuropathy, acute extrapyramidal disorders (such as dystonia, dyskinesia, tongue protrusion, torticollis).

Cardiovascular: rarely, hypotension, electrocardiographic change.

Neuropsychiatric disorders: Neuropsychiatric changes including psychosis, delirium, anxiety, agitation, insomnia, confusion, hallucinations, personality changes, depression, and suicidal behavior.

Cardiac disorders: Hypotension, electrocardiographic changes (particularly, inversion or depression of the T-wave with widening of the QRS complex), and cardiomyopathy (which may result in cardiac failure and in some cases a fatal outcome). Cardiac arrhythmias, conduction disorders such as bundle branch block / atrio-ventricular block, QT interval prolongation, torsade de pointes, ventricular tachycardia and ventricular fibrillation have been reported with therapeutic doses of chloroquine as well as with overdose. The risk is greater if chloroquine is administered at high doses. Fatal cases have been reported (see PRECAUTIONS, Cardiac Effects and SYMPTOMS AND TREATMENT OF OVERDOSE).

SYMPTOMS AND TREATMENT OF OVERDOSE

As chloroquine is very rapidly and completely absorbed after ingestion, and in accidental overdosage, or rarely with lower doses in hypersensitive patients, toxic doses may be fatal. As little as 1 g may be fatal in children. Toxic symptoms may occur within minutes. These consist of headache, drowsiness, visual disturbances, nausea, vomiting, cardiovascular collapse, and convulsions followed by sudden and early respiratory and cardiac arrest. The electrocardiogram (ECG) may reveal atrial standstill, nodal rhythm, prolonged intraventricular conduction time, and progressive bradycardia leading to ventricular fibrillation and/or arrest. Cases of extrapyramidal disorders have also been reported in the context of chloroquine overdose.

Treatment is symptomatic and must be prompt with immediate evacuation of the stomach by emesis (at home, before transportation to the hospital) or gastric lavage until the

stomach is completely emptied. Finely-powdered, activated charcoal, if introduced by the stomach tube after lavage within 30 minutes after ingestion of the antimalarial, may inhibit further intestinal absorption of the drug. To be effective, the dose of activated charcoal should be at least 5 times the estimated dose of chloroquine ingested.

Convulsions, if present, should be controlled before attempting gastric lavage. If due to cerebral stimulation, cautious administration of an ultra short-acting barbiturate may be tried but, if due to anoxia it should be corrected by oxygen administration, artificial respiration or, in shock with hypotension, by vasopressor therapy. Because of the importance of supporting respiration, tracheal intubation or tracheostomy, followed by gastric lavage, may also be necessary. Peritoneal dialysis and exchange transfusions have also been suggested to reduce the level of the drug in the blood.

A patient who survives the acute phase and is asymptomatic should be closely observed for at least 6 hours. Fluids may be forced, and sufficient ammonium chloride (8 g daily in divided doses for adults) may be administered for a few days to acidify the urine to help promote urinary excretion in cases of both overdose or sensitivity.

For management of a suspected drug overdose, contact your regional poison control centre.

DOSAGE AND ADMINISTRATION

The dosage of TEVA-CHLOROQUINE (chloroquine phosphate) is often expressed or calculated as the base. Each 250 mg tablet of TEVA-CHLOROQUINE is equivalent to 155 mg chloroquine base. In infants and children the dosage is preferably calculated on the body weight.

Suppressive treatment of malaria

In adults, 500 mg (310 mg base) on exactly the same day of each week.

In infants and children the weekly suppressive dosage is 5 mg/kg (calculated as base), but should not exceed the adult dose regardless of weight.

If circumstances permit, suppressive therapy should begin 2 weeks prior to exposure. However, failing this in adults, an initial double (loading) dose of 1 g (620 mg base), or in children 10 mg base/kg may be taken in 2 divided doses, 6 hours apart. The suppressive therapy should be continued for 8 weeks after leaving the endemic area.

Curative treatment of acute attack of malaria

In adults, an initial dose of 1 g (620 mg base) followed by an additional 500 mg (310 mg base) after 6 to 8 hours and a single dose of 500 (310 mg base) on each of 2 consecutive days. This represents a total dose of 2.5 g chloroquine phosphate or 10 tablets in 3 days.

The dosage for adults may also be calculated on the basis of body weight; this method is preferred for infants and children. A total dose representing 25 mg/kg (calculated as base) administered in 3 days, as follows:

First dose: 10 mg base per kg (but not exceeding a single dose of 620 mg base).

Second dose: 5 mg base per kg (but not exceeding a single dose of 310 mg base) 6 hours after 1st dose.

Third dose: 5 mg base per kg 18 hours after 2nd dose.

Fourth dose: 5 mg base per kg 24 hours after 3rd dose.

For radical cure of vivax and malariae concomitant therapy with an 8-aminoquinoline compound is necessary.

Treatment of extraintestinal amebiasis

Adults, 1 g (620 mg base) daily for 2 days, followed by 500 mg (310 mg base) daily for at least 2 to 3 weeks. Treatment is usually combined with an effective intestinal amebicide.

DOSAGE FORMS

TEVA-CHLOROQUINE Tablet, 250 mg: White, round, bi-convex, scored on one side and plain on the reverse, compressed tablet contains: chloroquine phosphate USP 250 mg (equivalent to 155 mg chloroquine base). Supplied in bottles of 100.

Non-Medicinal Ingredients: Dibasic calcium phosphate (dihydrate), lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch.

STORAGE

Store 15°C to 30°C. Keep out of reach and sight of children.

REFERENCE

1. Chloroquine Phosphate Tablets, USP 250 mg, United States Prescribing Information, Ipca Laboratories Ltd. January 2019.

PATIENT MEDICATION INFORMATION

PrTEVA-CHLOROQUINE (Chloroquine Phosphate Tablet)

Read this carefully before you start taking **TEVA-CHLOROQUINE** 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 **TEVA-CHLOROQUINE**.

What is TEVA-CHLOROQUINE used for?

- The prevention and treatment of certain forms of **Malaria**: an infection caused by parasites in your red blood cells.
- The treatment of **Extraintestinal Amoebiasis**: an infection caused by parasites.

How does TEVA-CHLOROQUINE work?

TEVA-CHLOROQUINE prevents certain parasites from growing in your red blood cells.

What are the ingredients in TEVA-CHLOROQUINE?

Medicinal ingredients: Chloroquine phosphate

Non-medicinal ingredients: Dibasic calcium phosphate (dihydrate), lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch.

TEVA-CHLOROQUINE comes in the following dosage forms:

Tablet, 250 mg

Do not use TEVA-CHLOROQUINE if you:

- are allergic to chloroquine or any of the other ingredients used in TEVA-CHLOROQUINE
- have retinal or visual field changes. You should tell your doctor right away if you have any problems with your vision.
- have had an allergic reaction to 4-aminoquinoline compounds such as other anti-malarial drugs.

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

- are allergic or sensitive to a drug called to quinine.
- have retinopathy or any visual problems.
- have weakness in your muscles, especially in the knees or ankles.
- have a skin disease called psoriasis.
- have liver disease or kidney.
- have alcoholism.
- have a genetic red blood cell disease known as “glucose-6-phosphate

dehydrogenase deficiency”.

- are pregnant, or you are planning to get pregnant. TEVA-CHLOROQUINE may be passed to your unborn baby. TEVA-CHLOROQUINE may harm your unborn baby. Your doctor will evaluate the benefit and risk of using TEVA-CHLOROQUINE during pregnancy.
- are breastfeeding. TEVA-CHLOROQUINE passes into breast milk in small amounts. Talk to your doctor about the risks TEVA-CHLOROQUINE can have on your baby.
- have heart disease or history of heart disease

Other warnings you should know about:

TEVA-CHLOROQUINE can be seriously harmful or fatal to children if taken incorrectly. Keep TEVA-CHLOROQUINE out of the reach and sight of children.

If you take TEVA-CHLOROQUINE for a long period, your doctor should conduct complete blood cell counts regularly. Your doctor may change or stop treatment if you develop any new blood disorders.

If you have heart disease or a history of heart disease, taking TEVA-CHLOROQUINE at high doses for a long period is risk. You should monitor for signs and symptoms of heart discomfort and discontinue chloroquine, with the advice of the healthcare professional.

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

How to take TEVA-CHLOROQUINE:

Usual dose:

The dosage of TEVA-CHLOROQUINE (chloroquine phosphate) is often expressed or calculated as the base. Each 250 mg tablet of TEVA-CHLOROQUINE is equivalent to 155 mg chloroquine base. In infants and children the dosage is preferably calculated on the body weight.

Adults:

Condition	Recommended dose	
Malaria	Suppression/ Prevention:	Start therapy 2 weeks prior to exposure. Take 1 tablet a week on exactly the same day of the week.
		If you do not start therapy 2 weeks prior to exposure, a double dose of 2 tablets may be taken, followed by 2 more tablets in 6 hours. Continue this therapy for 8 weeks after leaving the endemic area.
	Treatment:	Initially, take 4 tablets, followed by 2 tablets in 6 hours. Then take 2 tablets on the second and third

		days, or as directed by your healthcare professional.
Extraintestinal amebiasis	Treatment	Take 4 tablets a day for 2 days. Then take 2 tablets a day for at least 2 to 3 weeks. Treatment is usually combined with an effective intestinal amebicide.

Infants and Children:

Your doctor will tell you how much TEVA-CHLOROQUINE to give your child based on your child’s body weight.

Overdose:

Taking too much TEVA-CHLOROQUINE is dangerous and can lead to death. You could have symptoms of overdose within 30 minutes after taking it. Taking too much TEVA-CHLOROQUINE is also dangerous for children.

Symptoms of overdose include:

- headache
- feeling drowsy
- vision problems, like seeing blurry or in double
- nausea or vomiting
- heart problems like uneven heartbeats or rapid heartbeats
- fainting
- convulsions
- serious trouble breathing

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

Missed Dose:

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, skip the one you missed and take only the regularly scheduled dose. **Never take a double dose.**

What are possible side effects from using TEVA-CHLOROQUINE?

These are not all the possible side effects you may feel when taking TEVA-CHLOROQUINE. If you experience any side effects not listed here, contact your healthcare professional.

- Nausea, vomiting

- Stomach pain, stomach cramps
- Diarrhea
- Reduced hearing or ringing in the ears
- Itching, blemishes and change in skin colour
- Hair loss
- Nervous disorder symptoms such as anxiety, confusion, hallucinations, personality changes, depression, and suicidal behavior
- Heart Problems

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	
COMMON			
<u>Anorexia</u> : loss or lack of appetite		✓	
<u>Visual problems and damage to the retina of the eye</u> : blurred vision, seeing halos around lights, especially at night. Seeing light flashes and streaks. Night blindness with difficulty seeing at night or in poor light. Visual field loss including blind spots or blind areas in your vision. Change in eye colour. Difficulty focusing your eyes, or skipping words when reading.		✓	
Headache	✓		
Convulsive Seizures : spasms, shaking or fits			✓
RARE			
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)	✓		

If you have a troublesome symptom or side effect that is not listed here or 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 15°C to 30°C. Keep out of reach and sight of children.

If you want more information about TEVA-CHLOROQUINE:

- Talk to your healthcare professional.
- Find the Prescribing Information that is prepared for healthcare professionals by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>).
- Find the Prescribing Information on the manufacturer's website <http://www.tevacanada.com>; or by calling 1-800-268-4127 ext. 3; or email druginfo@tevacanada.com.

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