

CONSUMER INFORMATION

FACTS ON PRO-HYDROXYQUINE
(Hydroxychloroquine Sulfate Tablets USP)

Generic name: Hydroxychloroquine (hye-drox-ee-KLOR-oh-kwin)
Brand name: PRO-HYDROXYQUINE

Before you begin taking PRO-HYDROXYQUINE, please read the information in this leaflet carefully and completely. Keep this information with your other health records to read again as necessary.

Keep this medication out of reach of infants and small children. If you think an infant or small child has swallowed even one pill, immediately take them to the nearest hospital emergency room or dial "911" on your telephone.

WHAT YOU NEED TO KNOW BEFORE YOU BEGIN TAKING PRO-HYDROXYQUINE

- Do not take PRO-HYDROXYQUINE if you are allergic to hydroxychloroquine sulfate, to any of the other ingredients of PRO-HYDROXYQUINE or any similar drugs such as chloroquine.
- If you are taking digoxin (a medicine used to treat heart disease) or drugs for diabetes, their dose may need to be reduced.
- Cases of weakening of the heart muscle, resulting in heart failure and in some cases in death, have been reported in patients treated with PRO-HYDROXYQUINE. Talk to your doctor if you have symptoms such as breathlessness, swelling of the legs, irregular heart beat or fatigue and dizziness.
- PRO-HYDROXYQUINE crosses the placenta (the organ that allows the mother's oxygen and nutrients to pass to the unborn baby); you should tell your doctor if you are pregnant or planning to get pregnant.
- PRO-HYDROXYQUINE passes to breast milk; you should tell your doctor if you are breast feeding.
- Do not take PRO-HYDROXYQUINE if you have retinopathy (eye problem affecting the retina). PRO-HYDROXYQUINE may cause irreversible damage to the retina (the back of the eye where vision is created). You are required to have an eye exam before taking PRO-HYDROXYQUINE, then a follow-up as often as needed while taking PRO-HYDROXYQUINE. You should contact your doctor immediately if you experience any of the following visual problems: blurred vision, seeing halos around lights, especially at night, seeing light flashes and streaks, night blindness, visual field loss, change in eye colour (eye pigmentation), difficulty focusing eye, difficulty reading (skipped words).
- If you experience blurred vision when taking PRO-HYDROXYQUINE, do not drive or participate in activities requiring alertness.
- PRO-HYDROXYQUINE can cause hypoglycemia (low blood sugar); sometimes, hypoglycemia may be severe life-threatening, with loss of consciousness or requiring hospitalization. Talk to your doctor if you have symptoms such as sweating, shakiness, weakness, dizziness, fast heartbeat.
- Tell your doctor if you have/are:
 - liver or kidney disease
 - blood disease including a rare blood disease called porphyria
 - nervous system disease
 - a skin disease called psoriasis

- A genetic condition known as ‘glucose-6-phosphate dehydrogenase deficiency’
- allergic to chloroquine

This medication should only be used by the person for whom it is prescribed.

Protect your skin from the sun with appropriate clothing and sunscreen cream with a minimum SPF 30 rating when going outdoors.

ABOUT PRO-HYDROXYQUINE

PRO-HYDROXYQUINE is a white, capsule-shaped, biconvex film-coated tablet engraved ‘HCQ 200’ on one side and plain on the other.

Each pill contains 200 mg of hydroxychloroquine sulfate (which is the ‘active’ or ‘medicinal’ ingredient – the part of the pill that treats the disease or illness).

Non-medicinal ingredients: croscarmellose sodium, magnesium stearate, colloidal silicon dioxide, microcrystalline cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyethylene glycol, and titanium dioxide.

WHY PRO-HYDROXYQUINE IS PRESCRIBED AND ITS EXPECTED EFFECTS

PRO-HYDROXYQUINE is used for:

- The treatment of **rheumatoid arthritis (RA)**: Inflammation of the joints, characterized by stiffness, swelling and pain.
- The treatment of **Systemic Lupus Erythematosus (SLE)**: Disease where a person’s immune system mistakenly attacks healthy tissue; it can affect the skin, joints, kidneys, brain, and other organs.
- The treatment of **Discoid Lupus Erythematosus (DLE)**: similar to SLE except it only affects the skin with symptoms such as red rash or scaly patch.
- The prevention and treatment of acute attacks of certain form 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 .

How it works in the body to treat RA, SLE, and discoid lupus is unknown. Optimal improvement from PRO-HYDROXYQUINE may take up to six months.

HOW TO USE PRO-HYDROXYQUINE SAFE

PRO-HYDROXYQUINE should be taken with a glass of water on a full stomach or a glass of milk to reduce the chance of stomach upset.

If you forget to take a dose, take it as soon as you remember. But if it's within twelve hours of your next dose, skip the one you missed and take only the regularly scheduled dose. **Never take a double dose.**

Take PRO-HYDROXYQUINE exactly as prescribed by your doctor. Do not use PRO-HYDROXYQUINE after expiry date.

Should you have a serious change of health at any point while taking PRO-HYDROXYQUINE, see your doctor.

If PRO-HYDROXYQUINE completely controls your disease, talk to your doctor about the possibility of reducing your daily dose. Never reduce the dosage without talking with your doctor first.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

PRO-HYDROXYQUINE can cause side effects. Most side effects are mild to moderate. However, some may be serious and require treatment. Whether you will experience side effects before starting a medication therapy will be unknown to you and your physician. Each person taking a medication has a different experience, depending on their genetic makeup, past and present health status, and lifestyle. Talk to your doctor or pharmacist about any side effect while taking PRO-HYDROXYQUINE.

Serious side effects and what to do about them			
SYMPTOM / SIDE EFFECT	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Nausea, stomach pain, stomach cramps	√		
COMMON			
Diarrhea, loss or lack of appetite (anorexia)		√	
Vomiting		√	
Visual problem: blurred vision, difficulty focusing, seeing halos around lights, especially at night, seeing light flashes and streaks, night blindness, visual field loss, change in eye colour (eye pigmentation), difficulty focusing eye, difficulty reading (skipped words).		√	
Headache	√		
Rash, itchy rash		√	
Nervousness, emotional lability		√	
RARE			
Dizziness	√		
Hair loss, bleaching of hair, loss of skin pigment or increase in skin pigment (bluish-black colour)		√	
Ringing in the ears, decreased hearing		√	
Nerve and muscle disorders (e.g. tingling, numbness, burning pain, weakness, cramps, and spasms)		√	
NOT KNOWN			
Severe skin problem			√
Severe breathing problem (bronchospasm, angioedema)			√
Increased sensitivity to sunlight. Skin rash due to		√	

Serious side effects and what to do about them			
SYMPTOM / SIDE EFFECT	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
sunlight can be reduced by appropriate use of sunscreen creams			
Muscle weakness		√	
Permanent damage to vision		√	
Heart problems (e.g. breathlessness with exercise or even at rest, swelling of the legs, ankles and feet, irregular heartbeats that feel rapid or pounding, chest pain)		√	
Liver problems with symptoms such as: unusual tiredness, nausea, vomiting, abdominal pain, or jaundice (yellow discoloration of the eyes or skin)		√	
Lowered blood cell counts (e.g. fatigue, weakness, increase susceptibility to infections or bleeding)		√	
Convulsions			√
Psychosis (e.g. hallucinations, loss of contact with reality)		√	
Suicidal thoughts		√	
Hypoglycemia (low blood sugar) (e.g. sweating, shakiness, weakness, dizziness, fast heart beat, nausea, irritability, blurred vision, confusion, loss of consciousness)		√	
Long-lasting involuntary muscle contraction; impairment of voluntary movements, tremor			√

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](#);
- 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 0701E,
Ottawa, ON, K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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.

WHAT TO DO IF YOU 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.

Overdosing on PRO-HYDROXYQUINE is dangerous; symptoms may occur as early as within 30 minutes after ingestion.

Overdosage with PRO-HYDROXYQUINE is dangerous particularly in infants, as little as 1-2 grams having proved fatal.

Overdose symptoms include headache, drowsiness, blurred or double vision, rapid heart beats, fainting due to sudden decrease of blood flow and heart pump function, muscle weakness, convulsions and serious trouble breathing.

PRO-HYDROXYQUINE AND OTHER MEDICATIONS

Talk to your doctor if you are taking or going to take any other medications, including those obtained without prescription, vitamins and natural health products. Some medicines that may interact with PRO-HYDROXYQUINE are as follows:

- Digoxin. If you are taking both PRO-HYDROXYQUINE and digoxin, your doctor may decide to check the level of digoxin in your blood.
- Anti-diabetic drugs. If you are taking PRO-HYDROXYQUINE and are on a medication to control diabetes mellitus [high blood sugar], there is a risk of developing unusually low blood sugars, resulting in hunger pains, rapid heart rate, dizziness, and rarely, loss of consciousness. Your doctor may decide to reduce the doses of medications to control diabetes.
- Antiepileptic drugs
- Some antibiotics used for infections (aminoglycoside antibiotics) such as gentamycin, neomycin, tobramycin
- Neostigmine and pyridostigmine (medicines used to treat muscle disorders)
- Cimetidine (medicine used to treat heartburns)

- Ciclosporine (an immunosuppressant medication)
- Antacids. You should leave a gap of at least 4 hours between taking these medicines and PRO-HYDROXYQUINE
- Rabies vaccine
- Medicines that may affect the liver, the kidney, the skin or the eye
- Medicines that may cause irregular heart beat (e.g. amiodarone, moxifloxacin) or increase the risk of convulsions (e.g. antimalarials, mefloquine)
- Agalsidase (a medicine used to treat a rare genetic disease called Fabry disease)

PRO-HYDROXYQUINE has been used safely in combination with salicylates (aspirin), non steroidal anti-inflammatory medications, methotrexate and corticosteroids.

HOW TO STORE PRO-HYDROXYQUINE

- Keep out of reach of infants and small children.
- Store at controlled room temperature (15°C -30°C).

GENERAL INFORMATION ABOUT PRO-HYDROXYQUINE

This leaflet will not tell you everything you need to know about PRO-HYDROXYQUINE. For more information, please talk to your doctor or pharmacist.

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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