

**VALLABHBHAI PATEL CHEST INSTITUTE**  
UNIVERSITY OF DELHI  
DELHI-110 007

VPCI/Admn.II/DRO/Circular/4/2020/ 4694

31<sup>st</sup> March, 2020

**CIRCULAR**

**Subject: Constitution of Committee for use of hydroxyl-chlorquine as prophylaxis for SARS-CoV-2 infection – reg.**

It is to informed that the Institute vide circular no.VPCI/Admn.II/DRO/Circular/4/2020/4654 dated 25.03.2020 has constituted a committee to study the Advisory issued by the Department of Health Research, Ministry of Health & Family Welfare, Government of India and Director-General, ICMR for use of hydroxyl-chloroquine as prophylaxis for SARS-2 infection.

After studying the advisory, the Committee has suggested prophylaxis for:

1. Asymptomatic health care workers involved in the care of suspected or confirmed cases of COVID-19, and
2. Asymptomatic household contact of laboratory confirmed cases.

Further, the Committee has advised to circulate the recommendation for empiric use of hydroxyl-chloroquine for prophylaxis of SARS-CoV-2 infection with Hydroxy-chloroquine side effect to all concerned staff involved in the care of suspected or confirmed cases of COVID-19 and to take consent before giving the said drug.

In view of the above, all the concerned staff are requested to kindly go through the recommendations of the Ministry as well as drug's side effects (copy attached) and submit their written consent, if interested, to the undersigned latest by 07.04.2020 for further necessary action.

This issues with the approval of the competent authority.

  
Joint Registrar

To

All Faculty/HODs/Sectional Head

Copy to:

- PS to Director - for information to the Director.
- Master copy

## CONSENT FORM

I \_\_\_\_\_ AGREE TO TAKE HYDROXYCHLOROQUINE  
FOR PROPHYLAXIS OF SARS-COV-2 INFECTION. I AM AWARE THAT  
THERE IS NO SUBSTITUTE FOR INFECTION PREVENTION METHOD AND  
HAS GONE THROUGH THE SIDE EFFECT PROFILE ATTACHED.

SIGNATURE

NAME

DATE

## Recommendation for empiric use of hydroxy-chloroquine for prophylaxis of SARS-CoV-2 infection

### Background:

Hydroxy-chloroquine is found to be effective against coronavirus in laboratory studies and in-vivo studies. Its use in prophylaxis is derived from available evidence of benefit as treatment and supported by pre-clinical data. The following recommendation for the use of hydroxy-chloroquine as a prophylactic agent against SARS-CoV-2 infection is based on these considerations, as well as risk-benefit consideration, under exceptional circumstances that call for the protection of high-risk individuals.

The National Taskforce for COVID-19 recommends the use of hydroxy-chloroquine for prophylaxis of SARS-CoV-2 infection for selected individuals as follows:

### Eligible Individuals:

- Asymptomatic healthcare workers involved in the care of suspected or confirmed cases of COVID-19
- Asymptomatic household contacts of laboratory confirmed cases

### Dose:

- Asymptomatic healthcare workers involved in the care of suspected or confirmed cases of COVID-19: 400 mg twice a day on Day 1, followed by 400 mg once weekly for next 7 weeks; to be taken with meals
- Asymptomatic household contacts of laboratory confirmed cases: 400 mg twice a day on Day 1, followed by 400 mg once weekly for next 3 weeks; to be taken with meals

### Exclusion/contraindications:

- The drug is not recommended for prophylaxis in children under 15 years of age.
- The drug is contraindicated in persons with known case of retinopathy, known hypersensitivity to hydroxychloroquine, 4-aminoquinoline compounds

### Key considerations:

- The drug has to be given only on the prescription of a registered medical practitioner.
- Advised to consult with a physician for any adverse event or potential drug interaction before initiation of medication
- The prophylactic use of hydroxychloroquine to be coupled with the pharmacovigilance for adverse drug reactions through self-reporting using the Pharmacovigilance Program of India (PvPI) helpline/app.
- If anyone becomes symptomatic while on prophylaxis he/she should immediately contact the health facility, get tested as per national guidelines and follow the standard treatment protocol.
- All asymptomatic contacts of laboratory confirmed cases should remain in home quarantine as per the national guidelines, even if they are on prophylactic therapy.
- Simultaneously, proof of concept and pharmacokinetics studies be taken up expeditiously. Findings from these studies and other new evidence will guide any change in the recommendation.

### Advisory on the use of hydroxy-chloroquine as prophylaxis for SARS-CoV-2 infection

The **National Task force for COVID-19** constituted by Indian Council of Medical Research recommends the use of hydroxy- chloroquine for prophylaxis of SARS-CoV-2 infection for high risk population. Copy is annexed.

The Advisory provides for placing the following high risk population under chemoprophylaxis with hydroxy chloroquine:

- Asymptomatic Healthcare Workers involved in the care of suspected or confirmed cases of COVID-19
- Asymptomatic household contacts of laboratory confirmed cases

The protocol recommended by the National Task force has been approved by the Drug Controller General of India for restricted use in emergency situations.

While following the above recommendations, States should take note of the following:

- 1) **The placing of healthcare workers under chemoprophylaxis should not instill a sense of false security.** They should follow all prescribed public health measures such as frequent washing of hands, respiratory etiquettes, keeping a distance of minimum 1m and use of Personal protective equipment (wherever applicable).
- 2) They should self-monitor their health and report to health authorities immediately in the event of them becoming symptomatic.
- 3) The high risk contacts of a positive case placed under chemo prophylaxis, **should remain in home quarantine while on prophylactic therapy.**
- 4) As recommended by the said Task Force, the drug should only be given on the prescription of a registered medical practitioner. The contraindications mentioned in the recommendations should strictly be followed.
- 5) Apart from the symptoms of COVID-19 (fever, cough, breathing difficulty), if the person on chemo-prophylaxis develops any other symptoms, he should immediately seek medical treatment of the medical practitioner who has prescribed the chemoprophylaxis.

**It is reiterated that the intake of the above medicine should not in still sense of false security.**

# Hydroxychloroquine side effects

## Dermatologic

Rash

Pruritis

Pigmentary changes in skin and mucous membranes, bleaching of hair, and alopecia are usually reversible when therapy is discontinued.

Urticaria, angioedema, bullous eruptions including erythema multiforme, Steven-Johnson syndrome and toxic epidermal necrosis, Drug Rash with eosinophilia and Systemic Symptoms (DRESS syndrome) photosensitivity, exfoliative dermatitis, acute generalized exanthematous pustulosis (AGEP)

## Gastrointestinal

abdominal pain, nausea (10% or more)

Diarrhea, vomiting (1% to 10%)

## Hepatic

Abnormal LFT's (0.1% to 1%)

Fulminant hepatic failure

## Metabolic

Anorexia (1% to 10%)

Hypoglycemia, exacerbation or precipitation of porphyria

## Musculoskeletal

Sensorimotor disorders (0.1% to 1%)

Skeletal muscle myopathy or neuromyopathy, depression of tendon reflexes and abnormal nerve conduction studies

## **Nervous system**

Headache (10% or more)

Dizziness (0.1% to 1%)

Seizure, vertigo, nerve deafness, ataxia

## **Ocular**

Blurred vision (1% to 10%)

Retinopathy (0.1% to 1%) with changes in pigmentation and visual field defects, corneal changes haloes (e.g., blurring of vision, photophobia)

Maculopathies and macular degeneration (may be irreversible), extra-ocular muscle palsies (reversible), nystagmus

## **Psychiatric**

Affect liability (1% to 10%)

Nervousness (0.1% to 1%)

Psychosis, suicidal behaviour

## **Hypersensitivity**

Allergic reaction (urticaria, angioedema, bronchospasm), hypersensitivity myocarditis

## **Hematologic**

Bone-marrow depression, anemia, aplastic anaemia, agranulocytosis, leucopenia, thrombocytopenia

## **Cardiovascular**

Cardiomyopathy (can result in fatal cardiac failure), biventricular hypertrophy

## **Respiratory**

Bronchospasm

## Others

Tinnitus (0.1% to 1%)

Hearing loss

## CONTRAINDICATIONS / PRECAUTIONS

### Ocular disease, visual disturbance

Severe and irreversible retinal damage has been reported with the use of hydroxychloroquine.

#### Risk factors for retinal damage include

1. Daily doses more than 6.5 mg/kg (5 mg/kg base) of actual body weight
2. Durations of use greater than 5 years,
3. Subnormal glomerular filtration,
4. Use of concomitant drugs such as tamoxifen
5. Concurrent macular disease.

**Psoriasis or Porphyria** Hydroxychloroquine should be used with extreme caution in patients with psoriasis or porphyria because it has been shown to precipitate severe attacks.

### Alcoholism, hepatic disease

Hydroxychloroquine should be used with caution in patients with hepatic disease, a history of alcoholism, or in conjunction with known hepatotoxic drugs. A dosage reduction may be necessary in patients with hepatic disease and in those taking medicines known to affect the liver.

### GI disease

Hydroxychloroquine can cause gastric irritation and should be used with caution in patients with GI disease. It can be taken with meals or milk to minimize gastric irritation.

### G6PD deficiency

Administer hydroxychloroquine with caution in patients with glucose-6-phosphate dehydrogenase deficiency (G6PD deficiency) due to the risk of hemolysis.

### Myopathy, neurological disease

Hydroxychloroquine should be used with caution in patients with neurological disease and myopathy. Skeletal muscle myopathy or neuropathy leading to progressive weakness and atrophy of proximal muscle groups, depressed tendon reflexes, and abnormal nerve conduction have been reported.

### Children, infants, neonates

The safety and efficacy of the chronic use of hydroxychloroquine for systemic lupus erythematosus and juvenile idiopathic arthritis in children and infants have not been established. Children are especially sensitive to the 4-aminoquinoline compounds.

### Pregnancy

Guidelines recommend hydroxychloroquine as an alternative to chloroquine as a treatment option for acute malaria and for prophylaxis in pregnant women during all trimesters. Hydroxychloroquine may also be appropriate for pregnancies complicated by lupus.

### Breast-feeding

Use caution when administering hydroxychloroquine to breast-feeding women.

**Diabetes mellitus, hypoglycemia**

Use hydroxychloroquine with caution in patients with hypoglycemia or diabetes mellitus.

**Bradycardia, cardiac arrhythmias, cardiac disease, coronary artery disease, females, geriatric, heart failure, hypertension, hypocalcemia, hypokalemia, hypomagnesemia, long QT syndrome, malnutrition, myocardial infarction, QT prolongation, thyroid disease**

Hydroxychloroquine prolongs the QT interval. Use hydroxychloroquine with caution in patients with cardiac disease or other conditions that may increase the risk of QT prolongation including cardiac arrhythmias, congenital long QT syndrome, heart failure, bradycardia, myocardial infarction, hypertension, coronary artery disease, hypomagnesemia, hypokalemia, hypocalcemia, or in patients receiving medications known to prolong the QT interval or cause electrolyte imbalances. Females, geriatric patients, patients with diabetes, thyroid disease, malnutrition, liver impairment, or those who drink alcohol to excess may also be at increased risk for QT prolongation.