## Hydroxychloroquine

Presentation by
Primary Information Services www.primaryinfo.com mailto:primaryinfo@gmail.com


# Hydroxychloroquine (HCQ) is a medication used for the prevention and treatment of certain types of malaria. 

Malaria is common in areas such as Africa, South America, and Southern Asia. This medicine is not effective against all strains of malaria.
Hydroxychloroquine is also an antirheumatic medicine and is used to treat symptoms of rheumatoid arthritis and discoid or systemic lupus
erythematosus

## Products in the market place




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| Action Date |  | v | Submission | Supplement Categories or Approval Type | $\stackrel{\rightharpoonup}{*}$ | Letters, Reviews, Labels, Patient Package Insert | $\wedge$ | Note ${ }^{\text {人 }}$ |
| 01/05/2019 |  | SUPPL-51 |  | Labeling-Package Insert | Label (PDF) |  |  |  |
| 01/05/2019 |  | SUPPL-51 |  | Labeling-Container/Carton Labels | Label (PDF) |  |  |  |
| 01/27/2017 |  | SUPPL-47 |  | Labeling-Package Insert | Label (PDF) |  |  |  |
| 01/27/2017 |  | SUPPL-45 |  | Labeling-Package Insert | Label (PDF) |  |  |  |
| 01/27/2017 |  | SUPPL-37 |  | Labeling | Label (PDF) |  |  |  |
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Therapeutic Equivalents for NDA 009768

## PLAQUENIL

TABLET;ORAL; 200MG
TE Code $=A B$

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| Drug Name |  |  | Active Ingredients $\boldsymbol{\wedge}_{\boldsymbol{*}}$ | Strength | Dosage Form/Route | Marketing Status | $\text { RLD }^{\wedge}$ | TE Code | Application No. | Company ${ }^{\boldsymbol{*}}$ |
| HYDROXYCHLOROQUINE SULFATE |  |  | HYDROXYCHLOROQUINE SULFATE | 200MG | TABLET;ORAL | Prescription | No | $A B$ | 201691 | ALKALOIDA ZRT |
| HYDROXYCHLOROQUINE SULFATE |  |  | HYDROXYChLOROQUINE SULFATE | 200MG | TABLET;ORAL | Prescription | No | $A B$ | 210577 | AMNEAL <br> PHARMS CO |
| HYDROXYCHLOROQUINE SULFATE |  |  | HYDROXYCHLOROQUINE SULFATE | 200MG | TABLET;ORAL | Prescription | No | $A B$ | 210441 | APPCO |
| HYDROXYCHLOROQUINE SULFATE |  |  | HYDROXYCHLOROQUINE SULFATE | 200MG | TABLET;ORAL | Prescription | No | $A B$ | 040760 | HIKMA PHARMS |
| HYDROXYCHLOROQUINE SULFATE |  |  | HYDROXYCHLOROQUINE SULFATE | 200MG | TABLET;ORAL | Prescription | No | $A B$ | 040766 | IPCA LABS LTD |

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## Hydroxychloroquine (7)

Other Names: HCQ, Plaquenil, hydroxychloroquine sulfate

Drug Class: Immune Modulators
Molecular Formula: $\mathrm{C}_{18} \mathrm{H}_{26} \mathrm{Cl} \mathrm{N}_{3} \mathrm{O}$
Registry Number. 118-42-3 (CAS)
Chemical Name: Ethanol, 2-((4-((7-chloro-4-quinolinyl)amino)pentyl)ethylamino)-
Chemical Class: 4-aminoquinoline
Phase of Development: Hydroxychloroquine is in Phase II development as an immune modulator for HIV treatment.

Chemical Image: (Click to enlarge)
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+ Patient Version
- Health Professional

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## FDA frees India's Ipca from import ban so it can ship unproven COVID-19 treatments

by Eric Palmer | Mar 23, 2020 10:55am

## NXP ${ }^{\text {i.MX }}$ 6ULL

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## Google Patents

## Preparation method of hydroxychloroquine sulfate

## Abstract

The invention discloses a preparation method of hydroxychloroquine sulfate．The preparation method is characterized by comprising the following steps：condensing 4，7－dichloroquinoline serving as an initial raw material and a hydroxychloroquine side chain under the action of a catalyst， so as to obtain hydroxychloroquine；and reacting hydroxychloroquine with sulfuric acid，so as to prepare the hydroxychloroquine sulfate．According to the method disclosed by the invention，the defects in the prior art are overcome．The method has the advantages that the yield of the prepared hydroxychloroquine sulfate crude product is greater than or equal to $85 \%$ ，the yield of hydroxychloroquine sulfate is greater than or equal to $94 \%$ ；the total yield is greater than or equal to $80 \%$ ；the purity of the prepared hydroxychloroquine sulfate HPLC is greater than or equal to $99.6 \%$ ； the maximum single impurity is smaller than $0.1 \%$ ；the method accords with the requirements of United States pharmacopeia，is short in reaction step，and simple in the whole technological operation；and the obtained product is high in quality，high in yield，and relatively suitable for industrial production．

CN104230803A
China

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Other languages：Chinese
Inventor：唐明，龚大勇，杨忠鑫，刘英超，杨继斌，蔡中文，查正华，王亚川

## Worldwide applications

## 2014 CN

$\qquad$ (n) Fig. 1: Timeline of empiric introd $x$
$\square$ - nature.com/articles/s41584-020-0372-x/figures/1
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## hydroxychloroquine.

From: Mechanisms of action of hydroxychloroquine and chloroquine: implications for rheumatology
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This procedure has been okayed by Drug Controller General of India (DCGI) for "restricted use in emergency situations". The point to note here is that this recommendation is only for high-risk cases, and not for general use and one must not self-administer. The instructions are clear as to who all can be put under this.

ET Online | Last Updated: Mar 23, 2020, 07.11 PM IST


New Delhi: Amid rising coronavirus cases in the country, the national task force for COVID-19 constituted by Indian Council for Medical Research (ICMR) has recommended hydroxy-chloroquine as a


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(1)




## QUESTIONS

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