



SAFETY ALERT

DRAP SAFETY ALERT NO. 13

SAFETY ALERT OF FALSIFIED CHLOROQUINE PRODUCTS CIRCULATING IN THE WHO REGION OF AFRICA.

Date: 15th April, 2020

Target Audience:

- Healthcare Professionals.
- Patients, consumers or caregivers.

Problem or Issue:

World Health Organization (WHO) Global Surveillance and Monitoring System for Substandard and Falsified (SF) Medical Products through a Medical Product Alert N°4/2020 informed about nine different confirmed falsified chloroquine products circulating in the WHO region of Africa. WHO stated that these nine products are confirmed as falsified, on the basis that they deliberately/fraudulently misrepresent their identity, composition or source. WHO team of SF products further informed that it can be noted that either, these falsified products do not contain the correct amount of the active pharmaceutical ingredient, based on the results of preliminary or full compendial analysis; or these products were not produced by the manufacturer whose name is stated on the product labels, and the variable data (batch number and dates) of the above products do not correspond to genuine manufacturing records; or the manufacturer whose name is stated on the product labels does not exist. WHO recommended increased vigilance within the supply chains of countries likely to be affected by these falsified products. Increased vigilance should include hospitals, clinics, health centres, wholesalers, distributors, pharmacies and any other suppliers of medical products.

Therapeutic Goods Affected:

Name: Nine different falsified chloroquine products, with the following different presentations:

IDENTIFIED IN	PRODUCT NAME	STATED MANUFACTURER	BATCH NUMBER	EXPIRY DATE	DATE OF MANUFACTURE
CAMEROON	Chloroquine Phosphate (100mg)	Jiangsu Pharmaceutical Inc.	660	05/2021	05/2017
	Chloroquine phosphate (250mg)	Jiangsu Pharmaceutical Inc.	660	09/2022	09/2018
	Chloroquine Phosphate 250mg	Astral pharmaceuticals	EBT 2542	10/2022	01/2019
DEMOCRATIC REPUBLIC OF CONGO	COLORQUINE 250mg	Dawa Limited	1605059	04/2023	05/2019
	Chloroquine Phosphate 250mg	Brown & Burk Pharmaceutical Limited	065622	11/2022	11/2018
NIGER	Samquine 100 (100mg)	<i>None indicated</i>	NBJT01	Oct-2022	Nov-2019
	Chloroquine phosphate tablets B.P 100mg	<i>None indicated</i>	HV1116	May 2023	June 2019
	Chloroquine phosphate tablets B.P 100mg	<i>None indicated</i>	NBJT02	Oct-2022	Nov-2019
	Niruquine (100mg)	<i>None indicated</i>	<i>Unknown</i>	08/2022	09/2019





Advice for Patient, Healthcare Professionals and Other Stakeholders:-

Those patients, who are using any of above falsified product, should immediately stop it. If the patient has taken any of these falsified medical products, and has suffer an adverse event, should immediately seek the advice from a qualified healthcare professional, and ensure that they report the incident to Pakistan National Pharmacovigilance Centre, Drug Regulatory Authority of Pakistan. All drugs must be obtained from authentic and reliable sources. Their authenticity and condition should be carefully checked. Healthcare professionals are requested to ensure that necessary information related to the above products are reported to them by the patient and is subsequently reported to the Pakistan National pharmacovigilance Centre, DRAP, Islamabad. Other concerned stakeholders are requested to take further necessary action on their part.

Both healthcare professionals and patients are requested to report any suspected adverse drug reactions to **Pakistan National Pharmacovigilance Centre**, Drug Regulatory Authority of Pakistan through **DRAP Med Vigilance e-reporting system** [http://: https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PK](http://https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PK) or at npc@dra.gov.pk.

FOR FURTHER DETAILS SEE THE ENCLOSURES.



Ref. RPQ/REG/ISF/Alert N°4.2020

09 April 2020

Medical Product Alert N°4/2020

Falsified chloroquine products circulating in the WHO region of Africa

This Medical Product Alert relates to a number of confirmed falsified chloroquine products circulating in the WHO region of Africa. Please note that this Medical Product Alert n°4/2020 will be updated as new reports of falsified chloroquine are received and validated by WHO.

Between 31 March and 2 April 2020, the WHO [global surveillance and monitoring system on substandard and falsified \(SF\) medical products](#) received nine reports of confirmed falsified chloroquine products from three countries. All reported products were identified at patient level and all have been confirmed as falsified.

This WHO medical product alert N°4/2020 refers to nine different falsified chloroquine products, with different presentations (see Table 1). It is important to note that widespread vigilance is required from all countries, regardless of where the product was originally identified.

Table 1: List of identified falsified chloroquine products, subject of WHO Alert N°4/2020

IDENTIFIED IN	PRODUCT NAME	STATED MANUFACTURER	BATCH NUMBER	EXPIRY DATE	DATE OF MANUFACTURE
CAMEROON	Chloroquine Phosphate (100mg)	Jiangsu Pharmaceutical Inc.	660	05/2021	05/2017
	Chloroquine phosphate (250mg)	Jiangsu Pharmaceutical Inc.	660	09/2022	09/2018
	Chloroquine Phosphate 250mg	Astral pharmaceuticals	EBT 2542	10/2022	01/2019
DEMOCRATIC REPUBLIC OF CONGO	CLOROQUINE 250mg	Dawa Limited	1605059	04/2023	05/2019
	Chloroquine Phosphate 250mg	Brown & Burk Pharmaceutical Limited	065622	11/2022	11/2018
NIGER	Samquine 100 (100mg)	<i>None indicated</i>	NBJT01	Oct-2022	Nov-2019
	Chloroquine phosphate tablets B.P 100mg	<i>None indicated</i>	HV1116	May 2023	June 2019
	Chloroquine phosphate tablets B.P 100mg	<i>None indicated</i>	NBJT02	Oct-2022	Nov-2019
	Niruquine (100mg)	<i>None indicated</i>	<i>Unknown</i>	08/2022	09/2019

All the products listed in Table 1 are confirmed as falsified, on the basis that they deliberately/fraudulently misrepresent their identity, composition or source. Indeed, it can be noted that:

- EITHER: the products do not contain the correct amount of the active pharmaceutical ingredient, based on the results of preliminary or full compendial analysis;
- AND/OR: the products were not produced by the manufacturer whose name is stated on the product labels, and the variable data (batch number and dates) of the above products do not correspond to genuine manufacturing records;
- AND/OR: the manufacturer whose name is stated on the product labels does not exist.

Chloroquine phosphate or sulfate is referenced on the WHO Model List of Essential Medicines for the treatment of Plasmodium vivax infection (malaria). Large clinical trials are under way to generate the robust data needed to establish the efficacy and safety of chloroquine and hydroxychloroquine in the treatment of COVID-19. These medicines are currently authorized for malaria and certain autoimmune diseases and it is important that patients

do not face shortages caused by stockpiling or use outside the authorized indications. Both chloroquine and hydroxychloroquine can have serious side effects, especially at high doses or when combined with other medicines.

The [SOLIDARITY trial](#), led by WHO, is reviewing potential treatments for COVID-19. Please refer to [WHO medical product alert n°3/2020](#) for general information on falsified medical products in relation to the management of COVID-19.

For photographs of products listed in Table 1, please refer to the [WHO Medical Product Alert website](#), and to the annex of this medical product alert n°4/2020 (see pages 3-7).

WHO requests increased vigilance within the supply chains of countries likely to be affected by these falsified products. Increased vigilance should include hospitals, clinics, health centres, wholesalers, distributors, pharmacies and any other suppliers of medical products.

If you are in possession of the above products, please do not use. If you have used these falsified products, or if you suffer an adverse reaction/event having used these products, you are advised to seek immediate medical advice from a qualified healthcare professional, and to report the incident to the National Regulatory Authorities/National Pharmacovigilance Centre.

All medical products must be obtained from licensed, authentic and reliable sources. Their authenticity and condition should be carefully checked. Seek advice from a healthcare professional in case of doubt.

National regulatory/health authorities are advised to immediately notify WHO if these falsified products are discovered in their country. If you have any information concerning the manufacture, distribution, or supply of these products, please contact rapidalert@who.int.

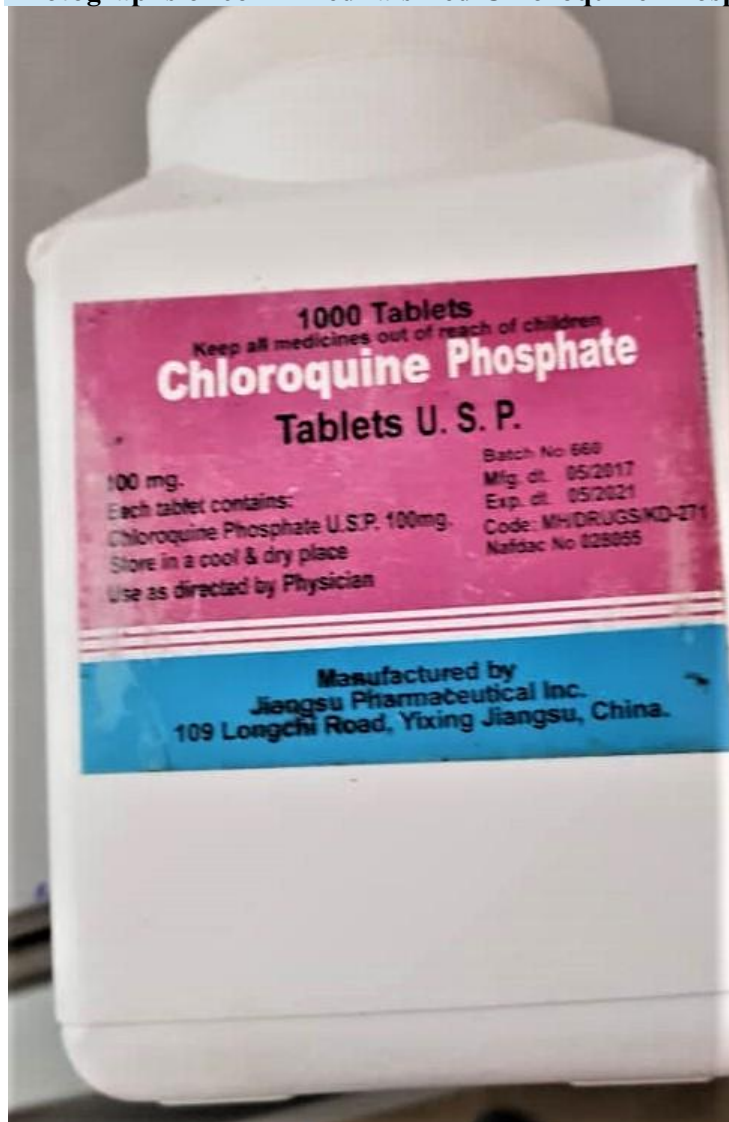
WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products

For more information, please visit: www.who.int/medicines/regulation/ssffc/en/

Annex: Photographs of falsified chloroquine products circulating in the WHO region of Africa, Medical Product Alert N°4/2020

CAMEROON

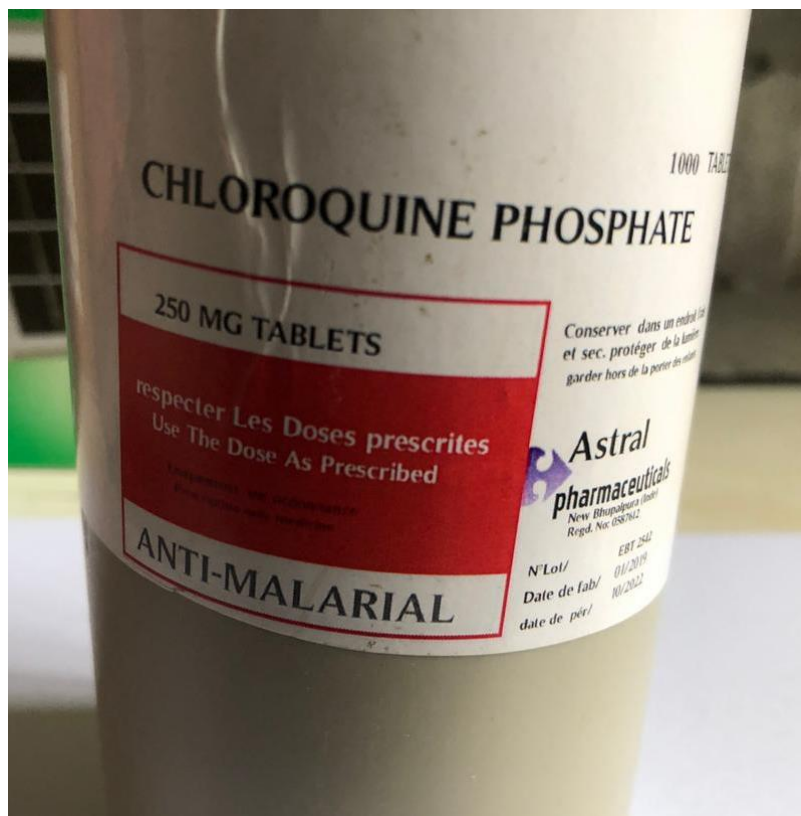
Photographs of confirmed falsified Chloroquine Phosphate (100mg)



Photographs of confirmed falsified Chloroquine Phosphate (250mg)



Photographs of confirmed falsified Chloroquine Phosphate 250mg



DEMOCRATIC REPUBLIC OF CONGO

Photographs of confirmed falsified CLOROQUINE 250MG



Photographs of confirmed falsified Chloroquine Phosphate 250mg



NIGER

Photographs of confirmed falsified Samquine 100 (100mg)



Photographs of confirmed falsified Chloroquine phosphate tablets B.P 100mg



Photographs of confirmed falsified Niruquine (100mg)

