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09 April 2020

UPDATE (of 9 June 2020) to Medical Product Alert n°4/2020

Medical Product Alert N°4/2020

Falsified chloroquine products circulating in the WHO regions of Africa and Europe

This Medical Product Alert relates to several confirmed falsified chloroquine products circulating in the WHO regions of Africa and Europe. New reports of falsified chloroquine which have been validated by WHO are included in this update.

Between 31 March and 14 April 2020, the WHO [global surveillance and monitoring system on substandard and falsified \(SF\) medical products](#) received 14 reports of confirmed falsified chloroquine products from 5 countries: Burkina Faso, Cameroon, Democratic Republic of Congo, France, and Niger. All reported products were identified at patient level and all have been confirmed as falsified.

Widespread vigilance is required from all countries, regardless of where the product was originally identified.

All the products (with photographs) listed in the annex 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.

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.

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.

If you are in possession of the above products, please do not use. If you have used these falsified products, or you suffered 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.

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.

ANNEX

Updated list of falsified chloroquine products, subject of WHO Alert N°4/2020, with additional products identified in Burkina Faso, Cameroun, and France

PRODUCT NAME	PRODUCT INFORMATION	IDENTIFIED IN	PHOTOGRAPHS
CHLOROQUINE PHOSPHATE (100MG)	Stated Manufacturer: Jiangsu Pharmaceutical Inc Batch N°: 660 Exp date: 05/2021 Mfg date: 05/2017	Cameroon	
CHLOROQUINE PHOSPHATE (250MG)	Stated Manufacturer: Jiangsu Pharmaceutical Inc Batch N°: 660 Exp date: 09/2022 Mfg date: 09/2022	Cameroon	
CHLOROQUINE PHOSPHATE 250MG	Stated Manufacturer: Astral pharmaceuticals Batch N°: EBT 2542 Exp date: 10/2022 Mfg date: 01/2019	Cameroon	

<p>CHLOROQUINE PHOSPHATE TABLETS (100MG)</p>	<p>Stated Manufacturer: Jiangsu Pharmaceutical Inc Batch N°: 660 Exp date: 08/2022 Mfg date: 08/2018</p>	<p>Cameroon</p>	
<p>CHLOROQUINE PHOSPHATE TABLETS (100MG)</p>	<p>Stated Manufacturer: Jiangsu Pharmaceutical Inc Batch N°: 660 Exp date: 04/2023 Mfg date: 05/2019</p>	<p>Cameroon</p>	
<p>CHLOROQUINE PHOSPHATE TABLETS BP 100MG</p>	<p>Stated Manufacturer: None indicated Batch N°: <i>Not legible</i> Exp date: 06/2022 Mfg date: 07/2019</p>	<p>Burkina Faso</p>	
<p>CHLOROQUINE PHOSPHATE TABLETS BP 100MG</p>	<p>Stated Manufacturer: None indicated Batch N°: ET9274 Exp date : 05/2022 Mfg date : 06/2019</p>	<p>Burkina Faso</p>	
<p>CHLOROQUINE PHOSPHATE TABLETS BP 100MG</p>	<p>Stated Manufacturer: None indicated Batch N°: 05 Exp date: 06/2022 Mfg date: 07/2019</p>	<p>Burkina Faso</p>	

<p>NIRUQUINE (100MG)</p>	<p>Stated Manufacturer: None indicated Batch N°: Not legible Exp date: 08/2022 Mfg date: 09/2019</p>	<p>Burkina Faso, France, Niger</p>	 <p>The image shows the packaging for Niruquine Chloroquine Phosphate Tablets 100 mg. The top part is a white box with green accents, labeled 'Niruquine Chloroquine Phosphate Tablets 100 mg', '10X10 Comprimés Tablets', and 'Antimalarial Tablets'. Below the box is a white insert card with the same product name, 'COMPOSITION: Chaque comprimé contient: Each uncoated tablet contains: Chloroquine phosphate B.P. 100 mg', 'Excipients: q.s.', 'Protect from heat, light and moisture. Store below 30°C. Dosage: As directed by the physician. Ne pas laisser à la portée des enfants. Keep out of reach of children.' It also includes 'Voie orale - For oral use Voir la notice intérieure see package insert.', 'Code No.: MVDROUSKD-398', 'Batch No.: See on Blister', 'Mfg. Date: 09/2019', 'Exp. Date: 08/2022', and a QR code.</p>
<p>CLOROQUINE 250MG</p>	<p>Stated Manufacturer: Dawa Limited Batch N°: 1605059 Exp date: 04/2023 Mfg date: 05/2019</p>	<p>Democratic Republic of Congo</p>	 <p>The image shows a white plastic container with a red lid for Cloroquine 250mg. The label is white with green and blue accents, stating '1000 Tablets/Comprimés/Comprimidos', 'CLOROQUINE 250mg', and 'Manufactured by: Dawa Limited, Plot No. 7/79/8, Baba Digo RD, Ruwaka PO BOX 166456-05076, Nairobi, Kenya'.</p>
<p>CHLOROQUINE PHOSPHATE 250MG</p>	<p>Stated Manufacturer: Brown & Burk Pharmaceutical Limited Batch N°: 065622 Exp date: 11/2022 Mfg date: 11/2018</p>	<p>Democratic Republic of Congo</p>	 <p>The image shows a white plastic bottle of Chloroquine Phosphate 250mg. The label is white with blue text, stating 'TABLETS 1000 COMPRIMÉS CHLOROQUINE PHOSPHATE 250', 'ANTI-MALARIA', 'Each tablet contains Chloroquine 250mg', 'Store in a dry place below 30°C and protected from light. Keep out of reach of children.', 'Manufactured by: Brown & Burk Pharmaceutical Limited, Ndolo, Kinshasa', and 'Batch No: 065622 Mfg. Date: 11/2018 Exp. Date: 11/2022'.</p>
<p>SAMQUINE 100 (100MG)</p>	<p>Stated Manufacturer: None indicated Batch N°: NBJT01 Exp date: Oct-2022 Mfg date: Nov-2019</p>	<p>France, Niger</p>	 <p>The image shows the packaging for Samquine 100 Chloroquine Phosphate Comprimés BP 100 MG. The box is yellow and pink, labeled 'SAMQUINE 100 CHLOROQUINE PHOSPHATE COMPRIMÉS BP 100 MG', '10 x 10 Tablets', and 'Antimalarial Tablets'. It features an illustration of a mosquito and several white tablets.</p>

CHLOROQUINE PHOSPHATE TABLETS B.P 100MG	Stated Manufacturer: None indicated Batch N°: NBJT02 Exp date: Oct-2022 Mfg date: Nov-2019	France, Niger	
CHLOROQUINE PHOSPHATE TABLETS B.P 100MG	Stated Manufacturer: None indicated Batch N°: HV1116 Exp date: May 2023 Mfg date: June 2019	Niger	

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

For more information, please visit: www.who.int/medicines/regulation/ssfc/en/ Email: rapidalert@who.int