

Ref. EMP/SAV/Alert N°10.2019

01 October 2019

Medical Product Alert N°10/2019

Falsified Quinine Bisulphate circulating in Uganda and Quinine Sulphate circulating in Central African Republic and Chad

This Medical Product Alert relates to four confirmed falsified products: quinine sulphate circulating in Central African Republic and Chad and quinine bisulphate circulating in Uganda. It should be noted that this is the second WHO Medical Product Alert issued on the same batch number of falsified quinine bisulphate circulating in the African region. Please refer to the previous [WHO Medical Product Alert N°2/2017](#) issued 27 July 2017. Quinine bisulphate and quinine sulphate are listed on the WHO Model List of Essential Medicines for management of severe malaria. This alert compiles details of four different falsified products that have been discovered at different times and locations over the past year. This repeated occurrence highlights the need for additional vigilance in Central and East Africa for such products that display common characteristics and distribution patterns.

1. QUININE SULPHATE BP 300mg identified in the Central African Republic

WHO was informed by a non-governmental organization (NGO) that this falsified quinine sulphate was found at patient level in the Central African Republic. At this stage, testing has not yet been conducted. Product details are listed in Table 1 below.

Table 1: Details of the falsified Quinine Sulphate BP 300mg, subject of WHO medical product alert N°10/2019

Product Name	QUININE SULPHATE BP 300mg
Stated Manufacturers	Phamachim Bulgaria and Enitop Pharmaceutical Nig. Ltd.
Batch Number	7711006
Manufacturing Date	8/2018
Expiry Date	7/2021
Declared Active Ingredients	Quinine sulphate BP 300 mg

Regarding the stated manufacturer, it should be noted that:

- The packaging indicates the product to be manufactured by “Enitop Pharmaceutical Nig. Ltd.” The National Agency for Food and Drug Administration and Control (NAFDAC) in Nigeria has confirmed that “Enitop Pharmaceutical Nig. Ltd.” is not registered as a manufacturer.
- The packaging indicates the product to be manufactured by “Phamachim Bulgaria”. This manufacturer does not exist.

It should also be noted that:

- At this stage, no adverse reactions have been reported to WHO.
- The packaging is in French language but displays numerous inconsistencies.
- The registration number stated on the packaging refers to the National Agency for Food and Drug Administration and Control (NAFDAC) in Nigeria. NAFDAC has confirmed that this is falsified.

2. QUININE SULPHATE BP 800mg identified in the Central African Republic

WHO was recently informed by a non-governmental organization (NGO) that this falsified quinine sulphate was found at patient level in the Central African Republic. Preliminary testing indicated that the product did not contain any of the stated active ingredient. Product details are listed in Table 2 below.

Table 2: Details of the falsified Quinine Sulphate BP 800mg, subject of WHO medical product alert N°10/2019

Product Name	QUININE SULPHATE BP 800mg
Stated Manufacturer	Phamachim, Bulgaria
Batch Number	00952005
Manufacturing Date	ft 06/2015
Expiry Date	pg 12/2020
Declared Active Ingredients	Quinine sulphate BP 800 mg

Regarding the stated manufacturer, it should be noted that:

- The packaging indicates the product to be manufactured by “Phamachim, Bulgaria”. This manufacturer does not exist.

It should also be noted that:

- Thin layer chromatography did not identify the expected active ingredient.
- At this stage, no adverse reactions have been reported to WHO.
- The packaging is in French language but displays numerous inconsistencies.
- The registration number stated on the packaging refers to the National Agency for Food and Drug Administration and Control (NAFDAC) in Nigeria. NAFDAC has confirmed that this is falsified.

3. QUININE Bisulphate 300mg. B.P. identified in Uganda

WHO was recently informed by the Uganda National Drug Authority that falsified quinine bisulphate was found at patient level in Uganda through routine post marketing surveillance on the quality of medical products in the market. Samples were sent for laboratory testing and the results were shared with WHO. Product details are listed in Table 3 below and are contained in the [Uganda National Drug Authority News Release](#).

Table 3: Details of the falsified Quinine Bisulphate 300mg. B.P., subject of WHO medical product alert N°10/2019

Product Name	QUININE Bisulphate 300mg. B.P.
Stated Manufacturer	Laboratory & Allied Ltd.
Batch Number	7422
Manufacturing Date	03-2017
Expiry Date	04-2021
Declared Active Ingredients	Quinine Bisulpahte B.P. 300mg

The above stated manufacturer has confirmed that:

- They did not manufacture this falsified version.
- The variable details on the product label do not correspond to the genuine manufacturer records.

It should also be noted that:

- Laboratory analysis did not identify the expected active ingredient.
- At this stage, no adverse reactions have been reported to WHO.
- There are labelling and packaging inconsistencies, including spelling errors.

4. QUININE SULPHATE BP 300mg identified in Chad

WHO was informed by a non-governmental organization (NGO) that this falsified quinine sulphate was found at patient level in Chad. Preliminary testing indicated that the product did not contain any of the stated active ingredient. Product details are listed in Table 4 below.

Table 4: Details of the falsified Quinine Sulphate BP 300mg, subject of WHO medical product alert N°10/2019

Product Name	QUININE SULPHATE BP 300mg
Stated Manufacturers	Phamachim Bulgaria and Enitop Pharmaceutical Nig. Ltd.
Batch Number	7711004
Manufacturing Date	5/2018
Expiry Date	4/2021
Declared Active Ingredients	Quinine sulphate BP 300 mg

Regarding the stated manufacturer, it should be noted that:

- The packaging indicates the product to be manufactured by “Enitop Pharmaceutical Nig. Ltd. The National Agency for Food and Drug Administration and Control (NAFDAC) in Nigeria has confirmed that “Enitop Pharmaceutical Nig. Ltd.” is not registered as a manufacturer.
- The packaging indicates the product to be manufactured by “Phamachim Bulgaria”. This manufacturer does not exist.

It should also be noted that:

- Thin layer chromatography did not identify the expected active ingredient.
- At this stage, no adverse reactions have been reported to WHO.
- The packaging is in French language but displays numerous inconsistencies.
- The registration number stated on the packaging refers to the National Agency for Food and Drug Administration and Control (NAFDAC) in Nigeria. NAFDAC has confirmed that this is falsified.

Photographs and advice to the public are available on the following pages.

Photographs of falsified quinine products subject of WHO Medical Product Alert N°10/2019

1. QUININE SULPHATE BP 300mg, batch 7711006 identified in the Central African Republic



2. QUININE SULPHATE BP 800mg, batch number 00952005 identified in the Central African Republic



3. QUININE Bisulphate 300mg. B.P., batch number 7422 identified in Uganda



4. QUININE SULPHATE BP 300mg, batch 7711004 identified in Chad



WHO requests increased vigilance within the supply chains of countries likely to be affected by these falsified medical 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 specific products, please do not use. If you have taken these falsified medical products, or if you suffer an adverse event or an unexpected lack of efficacy, please seek immediate advice from a qualified healthcare professional, and ensure they report the incident to your local Ministry of Health/National Medicines Regulatory Authorities/National Pharmacovigilance Centre.

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

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

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

For further information, please visit our website: www.who.int/medicines/regulation/ssffc/en/

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
ঔষধ প্রশাসন অধিদপ্তর
ঔষধ ভবন, মহাখালী, ঢাকা-১২১২
www.dgda.gov.bd

তারিখঃ ০৭/১০/২০১৯

নং-ডিজিডিএ/এলাট নোটিশ/এমসি-১৬/২০১৯/১০৬৭

-ঃ অফিস আদেশ :-


ঔষধ প্রশাসন অধিদপ্তরের মাঠ পর্যায়ের সকল কর্মকর্তাদের জানানো যাচ্ছে যে, বিশ্ব স্বাস্থ্য সংস্থা (WHO) সম্প্রতি মেডিক্যাল প্রোডাক্ট এলাট N° 10/2019- এ এই মর্মে সতর্ক করেছে যে, Phamachim Bulgaria and Enitop Pharmaceutical Nig. Ltd. কর্তৃক উৎপাদিত QUININE SULPHATE BP 300mg (Batch No: 7711006) ও Phamachim, Bulgaria কর্তৃক উৎপাদিত QUININE SULPHATE BP 800mg (Batch No: 00952005) সেন্ট্রাল আফ্রিকান প্রজাতন্ত্রে এর বাজারে Laboratory & Allied Ltd কর্তৃক উৎপাদিত QUININE Bisulphate 300mg. B.P.(Batch No: 7422) উগান্ডার বাজারে এবং QUININE SULPHATE BP 300mg Phamachim Bulgaria and Enitop Pharmaceutical Nig. Ltd. কর্তৃক উৎপাদিত (Batch No: 7711004) চাঁদ এর বাজারে নকল (Falsified) হিসেবে পাওয়া গেছে।

(সংযুক্ত কপিতে রসিন ছবি সহ টেবুলেটেড ফর্মে বিস্তারিত উল্লেখ করা আছে)।

Batch No	Manufacturing Date	Expiary Date
7711006	8/ 2018	07/2021
00952005	ft 06/2015	pg 12/2020
7422	03- 2017	04-2021
7711004	05/2018	04/2021

এমতাবস্থায়, উপরোল্লিখিত ০৪ (চার) টি ঔষধ বাজারে পাওয়া গেলে তা জব্দ করে প্রয়োজনীয় ব্যবস্থা গ্রহণের জন্য এতদ্বারা নির্দেশ প্রদান করা হল।

সংযুক্তিঃ ০৫ (পাঁচ) পাতা।



মোঃ আসরাফ হোসেন
সহকারী পরিচালক
ঔষধ প্রশাসন অধিদপ্তর
ফোনঃ ৯৮৮০৮৩১

E-mail: dgda.gov@gmail.com