Dirección Nacional de Medicamentos

República de El Salvador, América Central

UNIDAD DE INSPECCIÓN Y FISCALIZACIÓN

COMUNICACIÓN DE ALERTA

Santa Tecla, 08 de agosto de 2017

LA DIRECCIÓN NACIONAL DE MEDICAMENTOS (DNM) ALERTA SOBRE *PRODUCTO:* **QUININE Bisulphate 350mg. B.P**.

Nivel de alerta: 1
Nombre del producto: QUININE Bisulphate 350mg. B.P.
Presentación/Forma Farmacéutica: Frasco conteniendo tabletas recubiertas
Número de registro sanitario: No Presenta
Laboratorio Fabricante: Laboratory & Allied Ltd.
Lote(s): 7422
Fecha de vencimiento: 12/2018
Entidad emisora de la Alerta: OMS
País de Origen: África
Fecha de emisión de la Alerta: 27 de julio de 2017

Indicación/uso: El sulfato de quinina se encuentra indicado para el tratamiento de la malaria por Falciparum.

Descripción del problema encontrado: Producto Falsificado que no contiene el ingrediente farmacéutico activo declarado, no corresponde al registro genuino del fabricante. No se encontró registro sanitario alguno ni importaciones del producto, de acuerdo a la investigación realizada por la DNM.

La DNM alerta a toda la población a abstenerse de adquirir y/o suministrar éste producto, en virtud de que su uso representa un riesgo para la salud de la persona que lo consuma. En razón de que el producto **QUININE Bisulphate 350mg. B.P** No Cumple con los requerimientos de calidad que avale su seguridad, calidad y eficacia.

La DNM recomienda no adquirir este tipo de producto ya que pueden generar un riesgo a la salud. Así mismo recuerda adquirir los medicamentos en lugares autorizados por la DNM. Cualquier duda puede recurrir a ésta Dirección llamando al teléfono gratuito 136.

Se informa que la DNM continuará las acciones de vigilancia, como el aseguramiento de productos, para evitar la venta de los mismos porque representan un riesgo a la población.

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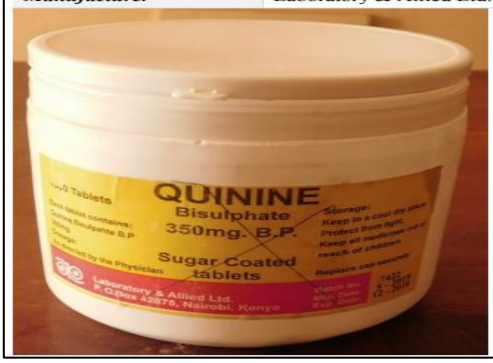
ANEXOS

2: QUININE Bisulphate 350mg. B.P., Laboratory & Allied Ltd.	
Product Name	**QUININE** Bisulphate 350mg. B.P.
Batch Number	7422
Expiry Date	12 - 2018
Manufacturing Date	5 - 2015
Manufacturer	Laboratory & Allied Ltd.



Link de información de alerta:

http://www.who.int/medicines/publications/drugalerts/drug_alert2-2017/en/

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Medical Product Alert N° 2/2017

Falsified Quinine Sulphate circulating in Africa

Falsified Quinine Sulphate circulating in Africa

This Medical Product Alert relates to the circulation of two confirmed falsified versions of Quinine Sulphate, in the Democratic Republic of the Congo, and containing zero active pharmaceutical ingredient.

Quinine Sulphate is used for the treatment of Falciparum Malaria in the region.

In April 2017, a local NGO discovered these products in pharmacies in the north-east of the Democratic Republic of the Congo. The products were submitted to laboratory testing with a WHO pre-qualified Quality Assurance laboratory. **This analysis showed that the two products did not contain any of the stated active pharmaceutical ingredient.**

The manufacturers indicated on the label of both products, Remedica and Laboratory & Allied Ltd., have stated that they did not manufacture these specific products: the variable details on the product label do not correspond to the genuine manufacturer records.

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pdf, 203kb

Full List of WHO Medical Product Alerts

WHO Medical Product Alerts – Background

SSFFC Medical Products

World Health Organization

Ref. RHT/SAV/Alert 2.2017 — 27 July 2017

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Details and photographs of both products are shown below:

1: Falsified Quinine Sulphate 300 , Remedica	
Product Name	Quinine Sulphate 300
Batch Number	15946
Expiry Date	03/18
Manufacturing Date	02/15
Manufacturer	Remedica

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2: Falsified QUININE Bisulphate 300mg. B.P., Laboratory&Allied	
Product Name	QUININE Bisulphate 300mg. B.P.
Batch Number	7422
Expiry Date	12-2018
Manufacturing Date	5-2015
Manufacturer	Laboratory & Allied Ltd

It is necessary to ensure that all medical products are obtained from authentic and reliable sources. Their authenticity and origin should be carefully checked and verified with manufacturers before use.

If you are in possession of these products, please do not use them. If you have taken this falsified product, or if you suffer an adverse event following its uptake, please seek immediate advice from a qualified healthcare professional, and report the incident to your local Ministry of Health/National Medicines Regulatory Authorities/National Pharmacovigilance Centre.

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, pharmacies and any other suppliers of medical products.

Health authorities are asked to immediately notify WHO if these falsified products are discovered in their country. If you have any information on their supply and/or distribution, please contact rapidalert@who.int

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

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

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