

QSM/MC/IEA.127

3 May 2013

Information Exchange System**Alert No. 127****Falsified batches of Coartem recently circulating in Western and Central Africa****Background**

In early 2013 a batch of falsified Coartem was discovered in Yaoundé, Cameroon, containing no active pharmaceutical ingredients.

Coartem is a fixed dose Artemesinin based combination therapy (ACT) (Artemether 20mg and Lumefantrine 120mg), used for the treatment of Plasmodium falciparum malaria. The genuine product is manufactured by Novartis and is a WHO pre-qualified medicine.

A pharmacist in Yaoundé requested Minilab testing as he suspected that the product was ineffective. The product failed screening by the minilab and was forwarded by an NGO to a WHO pre-qualified laboratory in Nairobi, Kenya, for more detailed analysis. Subsequent testing revealed that the product contained neither of the correct active pharmaceutical ingredients.

On 9 April 2013 WHO were informed by the NGO of the discovery of this falsified batch. Contact was subsequently established with all National Medicine Regulatory Authorities and Novartis. It has now been established that a second batch of falsified Coartem has been circulating in West and Central Africa recently.

Suspect medical products

The details of the falsified batches of Coartem are as follows.

Batch number: F1901
Expiry Date: 01.2014
Manufacturing Date: 01.2012

The packaging is in English and bears a falsified stamp of the Nigerian National Medicines Regulatory Agency, NAFDAC.

Batch Number: F2261
Expiry Date: 01.2014
Manufacturing Date: 01.2012

The packaging is in English and bears the falsified green leaf logo of the Affordable Medicines Facility – Malaria (AMFm) programme

These batches are packaged for adult use and for distribution within the public sector

These are both genuine Novartis batch numbers which have passed their expiry dates. No genuine Coartem bearing these batch numbers should now be in circulation.

Advice

Increased vigilance throughout the supply chain is strongly advised for these batches. Coartem should only be obtained from trusted, reliable and established legal sources.

If you have any questions or further information concerning this batch, or any is found or reported in your country, please contact rapidalert@who.int

Ref. RHT/SAV/MD/IEA.130

8th November 2013

Information Exchange System

Drug Alert No. 130

Falsified batches of Coartem recently circulating in Cameroon

Background

This drug alert serves as an update to WHO Drug Alert No. 127 of 3 May 2013 concerning falsified batches of Coartem that were circulating in Western and Central Africa.

<http://www.who.int/medicines/publications/drugalerts/drugalertindex/en/>.

Coartem is a fixed dose Artemesinin based combination therapy (ACT) (Artemether 20mg and Lumefantrine 120mg), used for the treatment of Plasmodium falciparum malaria. The genuine product is manufactured by Novartis and is a WHO pre-qualified medicine.

On 5 November 2013, Novartis informed WHO of further falsified versions of Coartem recently circulating in Cameroon.

Suspect medical products

Batch Number: NOF 2153
Manufacturing Date 01.2013
Expiry Date: 11. 2015

Batch Number F2929
Manufacturing Date: 01.2012
Expiry Date: 01.2016

The packaging of both batches is in English and bears the falsified green leaf logo of the Global Fund Affordable Medicines Facility – Malaria (AMFm) programme.

The details of the falsified batches of Coartem circulated by WHO in May 2013 are as follows.

Batch number: F1901
Manufacturing Date: 01.2012
Expiry Date: 01.2014

The packaging is in English and bears a falsified stamp of the Nigerian National Medicines Regulatory Agency, NAFDAC.

Batch Number: F2261
Manufacturing Date: 01.2012
Expiry Date: 01.2014

The packaging is in English and bears the falsified green leaf logo of the Affordable Medicines Facility – Malaria (AMFm) programme. Novartis has informed WHO that this batch has also been seen again recently in Cameroon.

All four batches are packaged for adult use and for distribution within the public sector. The falsified batches contain little or no active pharmaceutical ingredient and are therefore ineffective.

Advice

Some of these batches of falsified Coartem have been found in a number of West and Central African countries, both in hospitals and street markets. Increased vigilance throughout the region is strongly advised for these batches. Coartem should only be obtained from trusted, reliable and established legal sources. Hospitals, clinics, and pharmacies should check their stocks for these batches and report any suspicions to their national medicines regulatory authority

If you have any questions or further information concerning these batches, please contact rapidalert@who.int.