

Quality Assurance (QA) for Health Products

QA Information Notice

IN N° 2019-06	VOLUNTARY RECALL INITIATED BY Macleods FOR
Version: 19/06/2019	Moxifloxacin Dispersible tablets 100mg, - Batch No BMC5801A

Addressees

- Any person having products in stock, in transit or under custom clearance
- Any procurers, buyers with a pending order

Purpose

The GF QA is issuing this information notice to provide information that was transmitted by Macleods regarding a voluntary recall initiated on 01 June 2019 for the following product.

Identification of the product(s) and manufacturer

Name of Manufacturer	Macleods
INN Name	Moxifloxacin (hydrochloride)
Commercial Name(s)	Moxifloxacin hydrochloride Dispersible tablets, 100mg
Pharmaceutical form	Dispersible tablets
Strength	100 mg
Packaging & Pack size	Blister, Alu/Alu 10x10
Batch(es)	BMC5801A
Expiry Date	August 2020

Background

During ongoing stability studies organized by the manufacturer Macleods, out of specifications were identified regarding the results of the dissolution test. Following investigations, Macleods finally confirmed the non-compliance and decided to perform a voluntary recall of the above-mentioned Batch.

Nature of defect(s)

Details of defect or problem.	Non-compliant results founded for dissolution testing
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Is there any evidence or suspicion of a risk to public health?	Diminished availability of the active ingredient in the systemic circulation, diminished efficacy, potential increase of drug resistance, no immediate serious health related risk
Extent of the problem (eg. how many batches).	1 batch: BMC5801A 655 packs of 10x10 = 65500 tablets
Extent of distribution of the product / batch (es).	Worldwide distribution was foreseen but limited number of countries got impacted
Number of patients potentially impacted	No impacted patients known

Action/Investigations taken

- Procurement agent have been informed by the manufacturer and should forward the information regarding this recall to all impacted countries
- No Country supported by Global Fund Grants and using the GDF Stop-TB procurement mechanism could be identified
- GF to investigate if any direct procurement occurred

Next Steps

Based on the information available to date and until further notice, the following actions are recommended by GF QA:

- To put under quarantine the available stock of the impacted batches at regional and central level (class III-Wholesaler stage).
- To put under quarantine the impacted batches at port of entry and in transit, if applicable
- To report to the manufacturer/procurers (IDA) the available stock that was put under quarantine

Contacts

This IN does not require specific written response from PR. PRs should copy GF QA Team of any correspondence regarding the matter for follow-up.

Please direct the respective answers and any questions about this matter to the technical contacts listed below

Organisation	Name / Function	E-mail address
Global Fund	Amelie Darmon, QA Ass. Specialist	Amelie.Darmon@theglobalfund.org
Global Drug Facility	Nigorsulton Muzafarova, Product Quality Officer	nigorsultonm@stoptb.org



URGENT DRUG RECALL

Product Name	Expiry Date	Lot(s)
Moxifloxacin Hydrochloride Dispersible Tablets 100 mg	Aug 2020	BMC5801A

Dear Customer,

Macleods Pharmaceutical is initiating a voluntary wholesaler level recall on Moxifloxacin Hydrochloride Dispersible Tablets 100 mg.

This recall is based upon Macleods determination of out of specification results reported during stability study analysis. On the basis of medical and professional review, adverse safety or health hazard concerns are unlikely. Hence we are initiating Class III level recall.

Macleods Pharmaceutical requests that you immediately take the following actions:

- Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.
- In the event you have Recall product, please withhold the further distribution and notify to Macleods Pharmaceuticals Limited.

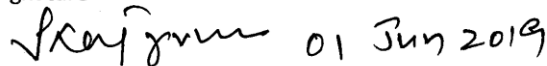
This action applies only to Moxifloxacin Hydrochloride Dispersible Tablets 100 mg Batch No. BMC5801A listed above. Only product from this lot will be accepted under the terms of this recall.

1. If you have any questions regarding this recall, please contact Macleods Pharmaceuticals Limited.

G-2, Mahakali Caves Road, Shanti Nagar, Andheri (East), Mumbai - 400093, INDIA,
Phone: + 91 22 61132900, Fax: 91 22 28304641

We regret any inconvenience and appreciate your immediate cooperation.

Signature



For Macleods Pharmaceuticals Limited.

**MACLEODS
PHARMACEUTICALS
LIMITED**

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