

# Sultanate of Oman

## Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control  
MUSCAT



سلطنة عُمان  
وزارة الصحة  
المديرية العامة للصيرورة  
والرقابة الدوائية  
مسقط

To:

Director General of Royal Hospital  
Director General of Khoula Hospital  
Director General of Medical Supplies (MOH)  
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Health Institutions)  
Director General of Health Services in all Governorates  
Director of Rational Use of Medicine (MOH)  
Hospital Director (Al Nahda Hospital)  
Hospital Director (Al Massara Hospital)  
The Head of Medical Services in SQU Hospital  
The Head of Medical Services in Royal Oman Police  
The Head of Medical Services in Ministry of Defence  
The Head of Medical Services in The Diwan  
The Head of Medical Services in The Sultan's Special Force  
The Head of Medical Services in Internal Security Services  
The Head of Medical Services in Petroleum Development of Oman  
The Head of Medical Services in LNG Oman  
Director of Pharmacy & Medical Stores in all Governorate (for distribution pls.)  
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No..59..... dated 09/09/18  
regarding the Batch recall of Amoclan Suspension 156mg/5ml & 312mg/5ml  
from Hikma Pharmaceuticals, Jordan.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Supdt. of Central Drug Information
- Head of Cordn. & FU
- M/s. Ibn Sina Pharmacy – to arrange recall of the above batches and let us know the total quantity recalled within ONE week. Please submit this information to Department of Pharmacovigilance & Drug Information through online e-portal (submission type 'Other').

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Circular No. 59 / 2018

29 -12-1439 H

09 -09-2018

### Recall of Batches

**Amoclan 156mg/5ml Suspension, B/No. 7790 & 8000**  
**Amoclan 312mg/5ml Suspension, B/No. 8217 & 8047**  
**M/s. Hikma Pharmaceuticals, Jordan**

We have decided to recall the following batches of Amoclan Suspension from M/s. Hikma Pharmaceuticals, Jordan, due to non-compliance with the specification. The samples from these batches were analysed by the Central Quality Control Laboratory (QCL) who found that the assay test result of Amoxycillin was below the company's specification limit hence QCL rejected these batches:

**Amoclan 156mg / 5ml Suspension, B/No. 7790 & 8000**  
**Amoclan 312 mg/ 5ml Suspension, B/No. 8217 & 8047**

Please do not dispense the above mentioned batches which should be returned to the local agent M/s. Ibn Sina Pharmacy under intimation to us.

The healthcare professionals are kindly requested to report any adverse events or side effects associated with the use of the above product or any other medicinal product to the Department of Pharmacovigilance & Drug Information in DGPA&DC.

  
Dr. Mohammed Hamdan Al Rubaie  
DIRECTOR GENERAL

