

# Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control

MUSCAT



سلطنة عمان  
وزارة الصحة  
المديرية العامة للصيدل  
والرقابة الدوائية  
مسقط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General Quality Assurance Centre, MOH

Director General of Engineering Affairs, MOH

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Director General of Quality Assurance Centre, 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

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 141/2020 dated 29/7/2020  
regarding Azithromycin review of QT prolongation in the context of COVID-19  
infection.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information

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Circular No. 141 / 2020

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29 -07-2020



سِلاطِنَة عُمان  
وَزارة الصِّحة  
المَدِينَة العَمانَة للصِّدائِكَة  
وَالرِّقَابَة الدَّوائِيَّة  
مَسَقَط

## Azithromycin review of QT prolongation in the context of COVID-19 infection

During routine pharmacovigilance activities, with special focus on medicinal products that could be used in the context of COVID-19 pandemic, an increased number of reports of QT prolongation events have been observed following the use of azithromycin. Thus, Pfizer has initiated a review of reports of QT prolongation in the context of COVID-19 infection.

This evaluation has revealed that during the time frame of the COVID-19 pandemic, there have been an increased number of cases reporting QT prolongation events when azithromycin has been administered concomitantly with hydroxychloroquine, in the context of COVID-19 infection. Data mining analyses indicated increased observed-to-expected reporting frequencies for QT prolongation events involving the combination of these two products, which exceeded that observed for the drugs when reported individually.

Azithromycin is an antibiotic indicated to treat patients with certain bacterial infections caused by susceptible organisms. Azithromycin is not approved for the treatment of COVID-19 or other viral infections. The current approved product information recommends that prescribers should consider the risk of QT prolongation, which can be fatal when weighing the risks and benefits of azithromycin for at-risk groups including patients currently receiving treatment with other active substances known to prolong the QT interval, and with clinical conditions predisposing to the onset of QT prolongation. Evaluation of the currently available data does not change the positive benefit-risk assessment for the use of azithromycin in its currently approved indications, while following relevant precautions of use.

Healthcare professionals are encouraged to report any adverse events suspected to be associated with 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

