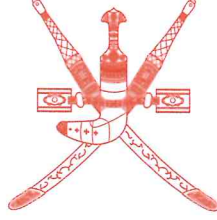


Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سِلْطَنَة عُومَانِ
وَزَارَة الصِّحَّة
وَالرِّقَابَة الْعَامَّة لِلصِّدْقِ
وَالرِّقَابَة الدَّوْلِيَّة
مَسْقَط

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
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 Circular No. 18..... dated 28/02/18 regarding US FDA's drug safety communication about Clarithromycin (Biaxin).

Copy to:

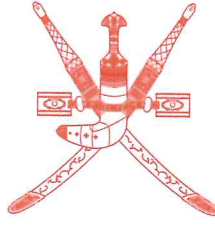
- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central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

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سلطنة عمان
وزارة الصحة
الديريته العامة للأدوية
والرقابة الدوائية
مسقط

Circular No. 18/ 2018

12 -06-1439 H
28 -08-2018

Clarithromycin (Biaxin): Drug safety communication – Potential increased risk of heart problems or death in patients with heart disease

Please be informed that the US FDA is advising caution before prescribing the antibiotic clarithromycin (Biaxin) to patients with heart disease because of a potential increased risk of heart problems or death that can occur years later. FDA's recommendation is based on a review of the results of a 10-year follow-up study of patients with coronary heart disease from a large clinical trial that first observed this safety issue.

The large clinical trial, called the CLARICOR trial, observed an unexpected increase in deaths among patients with coronary heart disease who received a two-week course of clarithromycin that became apparent after patients had been followed for one year or longer. There is no clear explanation for how clarithromycin would lead to more deaths than placebo. Some observational studies also found an increase in deaths or other serious heart-related problems, while others did not. All the studies had limitations in how they were designed. Of the six observational studies published to date in patients with or without coronary artery disease, two found evidence of long-term risks from clarithromycin, and four did not. Overall, results from the prospective, placebo-controlled CLARICOR trial provide the strongest evidence of the increase in risk compared to the observational study results. Based on these studies, FDA is unable to determine why the risk of death is greater for patients with heart disease.

As a result, FDA added a new warning about this increased risk of death in patients with heart disease, and advised prescribers to consider using other antibiotics in such patients. FDA also added the study results to the clarithromycin drug labels.

Clarithromycin is used to treat many types of infections affecting the skin, ears, sinuses, lungs, and other parts of the body, including Mycobacterium avium complex (MAC) infection, a type of lung infection that often affects people with human immunodeficiency virus (HIV). Clarithromycin is not approved to treat heart disease.

Healthcare professionals should be aware of these significant risks and weigh the benefits and risks of clarithromycin before prescribing it to any patient, particularly in patients with heart disease and even for short periods, and consider using other available antibiotics. Advise patients with heart disease of the signs and symptoms of cardiovascular problems, regardless of the medical condition for which they are being treated with clarithromycin.

Clarithromycin is registered in Oman in different brand names. The healthcare professionals are kindly requested to report any adverse events or side effects associated with the use of any medicinal product to the Department of Pharmacovigilance & Drug Information in DGPA&DC.

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

