Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs and Drug Control

MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة 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.....74/2019.....dated .....26/9/2019.....regarding Ranitidine.

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. Muscat Pharmacy & M/s. Al Hashar Phrmacy** – *to arrange recall of the above products and let us know the total quantity recalled, customers and the method of disposal of the recalled quantity, within ONE week. Please submit this information to Department of Pharmacovigilance & Drug Information through online e-portal (submission type 'Recall').*

dg-padc@moh.gov.om : ص.ب رقم : ٣٩٣ مسقط - الرمز البريدي : ١٠٠ ، هاتف : ٢٢٣٥٧١١١ ، فاكس : ٢٢٣٥٨٤٨٩، البريد الإلكتروني
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

Sultanate of Oman
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Circular No. 74 / 2019

26 -01-1441 H

26 -09-2019

Products Recall / Suspension of registration of products containing Ranitidine

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Reference to the US FDA's recent announcement that some ranitidine medicines contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA) at low levels. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests.

As a precautionary measure, we have decided to:

1. Suspend the registration of all products containing Ranitidine.
2. Recall all dosage forms of Zantac (Mfr: GSK) and Ranid (Mfr: Tabuk) due to the recent laboratory investigation results.

You are requested to stop dispensing all Zantac and Ranid dosage forms and return the available stock, if any, to the local agents M/s. Muscat Pharmacy & M/s. Al Hashar Pharmacy respectively, 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

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SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS &DRUG CONTROL

dg-padc@moh.gov.om : البريد الإلكتروني ، فاكس : ٢٢٣٥٨٤٨٩ ، هاتف : ٢٢٣٥٧١١١ ، الرمز البريدي : ١٠٠ ، مسقط - ص.ب رقم : ٣٩٣
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