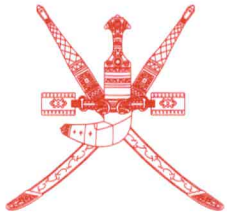
Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs and Drug Control

MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
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. Hospitals)
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.....110..... dated .....26/12/19..... regarding FDA's warning that serious breathing difficulties may occur in patients using Gabapentin or Pregabalin who have respiratory risk factors.

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

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

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Circular No. 110 / 2019

29 -04-1441 H
26 -12-2019

Neurontin, Gralise, Horizant (GABAPENTIN) and Lyrica, Lyrica CR (PREGABALIN) Drug Safety Communication – Serious Breathing Problems

The US Food & Drug Administration is warning that serious breathing difficulties may occur in patients using gabapentin (Neurontin, Gralise, Horizant) or pregabalin (Lyrica, Lyrica CR) who have respiratory risk factors. These include the use of opioid pain medicines and other drugs that depress the central nervous system, and conditions such as chronic obstructive pulmonary disease that reduce lung function. The elderly are also at higher risk.

FDA is requiring new warnings about the risk of respiratory depression to be added to the prescribing information of the gabapentinoids. FDA has also required the drug manufacturers to conduct clinical trials to further evaluate their abuse potential, particularly in combination with opioids, because misuse and abuse of these products together is increasing, and co-use may increase the risk of respiratory depression.

Gabapentinoids are FDA-approved to treat a variety of conditions including partial seizures and nerve pain from spinal cord injury, shingles, and diabetes. Other approved uses include fibromyalgia and restless legs syndrome.

RECOMMENDATION: Patients and caregivers should seek medical attention immediately if someone experiences symptoms of respiratory problems, because these can be life-threatening. Symptoms to watch for include:

- Confusion or disorientation
- Unusual dizziness or lightheadedness
- Extreme sleepiness or lethargy
- Slowed, shallow, or difficult breathing
- Unresponsiveness, which means a person doesn't answer or react normally or you can't wake them up
- Bluish-colored or tinted skin, especially on the lips, fingers, and toes

Always inform your health care professional about all the drugs you are taking, including prescription and over-the-counter medicines and other substances such as alcohol.

.....2.

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Circular No. 110/2019

Health care professionals should start gabapentinoids at the lowest dose and monitor patients for symptoms of respiratory depression and sedation when co-prescribing gabapentinoids with an opioid or other central nervous system depressant such as a benzodiazepine.

Pregabalin and Gabapentin are registered and available in Oman in different brands.

Healthcare professionals are encouraged to report any adverse events suspected to be associated with the above products 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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المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACY & DRUG CONTROL

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