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.31..... dated 25/04/18 regarding EMA's review of risk of dosing errors with methotrexate.

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

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : mohphar@omantel.net.om
P.O. Box : 393 Muscat, Postal code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : mohphar@omantel.net.om

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Circular No. 31 / 2018

09 -08-1439 H
25 -04-2018

EMA reviewing risk of dosing errors with methotrexate

Review prompted by continued reports of overdose

Please be informed that the The European Medicines Agency (EMA) has started a review of the risk of dosing errors with methotrexate medicines.

When used for inflammatory diseases, such as arthritis and psoriasis, methotrexate is taken once a week whereas for some types of cancer, the dose is higher and the medicine is used more frequently. Mistakes have led to some patients incorrectly receiving a dose every day instead of every week. As a result, patients have received too much of the medicine, with serious consequences in some cases.

The risk of dosing errors with methotrexate has been recognised for many years and several measures are already in place in some EU countries to reduce this risk, including the use of visual reminders on the medicine packs. However, a recent assessment1 found that serious adverse events related to overdose, including fatalities, are still occurring. The Spanish medicines regulator, AEMPS, therefore asked EMA to further investigate the reasons why dosing errors continue to occur in order to identify measures to prevent them.

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) will now examine the available evidence and recommend whether further measures are needed to minimise the risk of dosing errors. The PRAC will also take into account the work of bodies specialising in patient safety.

More about the medicine

Methotrexate medicines are used to treat cancers such as acute lymphoblastic leukaemia (ALL) and various inflammatory conditions, including rheumatoid arthritis, juvenile idiopathic arthritis, psoriasis, and psoriatic arthritis.

Methotrexate can be taken orally or given by injection.

Methotrexate is available in Oman in tablet form and as injectables. This is to urge the healthcare professionals to prevent this medication error by giving proper counseling to patients and care givers. 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.

A-S

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

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