

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سِلاطِنَةُ عُومَانِ
وَزَارَةُ الصِّحَّةِ
المديرية العامة للصحة
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.....²¹..... dated ^{5/3/2018}.....
regarding the voluntary batch recall of Megental Injection from
M/s.A.Menarini, Italy.

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 Cordin. & FU
- M/s. Al Hashar Pharmacy – to arrange **URGENT** recall of the above batches and let us know the total quantity recalled within **ONE** week.

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سلطنة عمان
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Circular No. 21 / 2018

17 -06-1439 H

05 -03-2018

Recall of Batches
MEGENTAL INJECTION 80mg 2ml Ampoules
M/s. A. Menarini, Italy

Please be informed that M/s. A. Menarini has voluntarily recalled the following batches of Megental 80mg 2 ml Ampoules exported to Oman. The company initiated the recall following receipts of an investigation summary of adverse effects of Gentamicin Sulfate transmitted by the API Gentamicin Sulfate manufacturer Fujian Fukang Pharmaceutical Co., Ltd which is used for Megental 80mg 2ml Ampoule finished product.

Batches: 1563 & 1564

In view of the above information, we have decided to recall the above product. You are kindly requested to return the available stock, if any, to the local agent M/s. Al Hashar Pharmacy LLC 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

