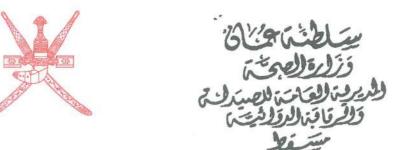
Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs and Drug Control





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...2.2. dated and Light Regarding NCMDR Field Safety Notice of Novocastra Liquid Mouse Monoclonal Antibody von Willebrand Factor (6.4M) from (mfr: Leica Biosystems).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- 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

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MUSCAT





Circular No. 228/2020

23 -4-1442 H

09 -12-2020

Field Safety Notice of Novocastra Liquid Mouse Monoclonal Antibody von Willebrand Factor (6.4M) from Leica

Source	NCMDR- National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15449
Product	Novocastra Liquid Mouse Monoclonal Antibody von Willebrand Factor.
Description	Haematology / Haemostasis / Immunohaematology / Histology / Cytology.
Manufacturer	Leica Biosystems.
Local Agent	Integrated Medical Solutions LLC.
The affected products	Lot Number: 6071415 Expiry Date: 30 Sep 2021.
Reason	The concentration of the affected product is lower at approximately 10ug/ml.
Action	 If the affected Lot has been used with Internal Quality Control (IQC) material as per good laboratory practice, there is no recommendation to investigate previously tested results. Should IQC material not be used then the laboratory may decide to investigate all results, which have utilized this material. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Meddevice@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL