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
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.....30..... dated .....24/03/2019..... regarding the risk of corneal haze associated with the Raindrop Near Vision Inlay.

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

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

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

Circular No. 30 / 2019

17-07-1440 H
24-03-2019

Increased risk of Corneal Haze associated with the Raindrop Near Vision Inlay: FDA Safety communication

The US Food & Drug Administration released a safety communication regarding the Raindrop Near Vision Inlay after a post-approval study found 75% of patients with the inlay developed haze in any location within the cornea. The Raindrop Near Vision Inlay is a transparent, curved hydrogel disc smaller than the eye of a needle. The device was designed to be surgically placed (implanted) into the cornea of one eye. FDA granted approval of this device in 2016 to ReVision Optics to improve near vision and offer an alternative to eyeglasses or contact lenses in healthy patients. The device is now owned by RVO 2.0, doing business as Optics Medical.

FDA's safety communication is to alert eye care providers and patients already implanted with the device of the increased risk of corneal haze (a type of cloudiness in the cornea due to inflammation) associated with the device. FDA is advising that eye care providers not implant Raindrop inlays and is working with Optics Medical to have all remaining product on the market recalled. Raindrop Inlays are no longer being distributed in the U.S.
People who undergo implantation of the Raindrop Near Vision Inlay device are at risk for the development of corneal haze that can affect clear vision. Haze can cause blurry vision or glare by clouding the cornea, or by changing the focusing power of the eye. The impact of haze on the patient's vision is dependent on the severity of haze and its location in the cornea.

Recommendations for Eye Care Providers:

- Do not implant Raindrop inlays.
- Contact the company for instructions on returning any unused product to the firm.
- Be aware of the new data from the ongoing post-approval study, which is showing high rates of corneal haze in both implanted and explanted patients, and an increasing rate of device removal.
- Monitor patients with the implant for the development of corneal haze.
- Monitor patients whose device has been explanted for the development of corneal haze.

Kindly check your stock and return the available quantity, if any, to the manufacturer/local agent.

Healthcare professionals are encouraged to report any adverse events suspected to be associated with the above device or any other medical device to:

Director of Medical Device Control
Directorate General of Pharmaceutical Affairs & Drug Control
Ministry of Health, PO Box 393, Muscat, PC-100, Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

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