Sultanate of Oman Ministry of Health Drug Safety Center Muscat



سلطنة عُمان وزارة الصحــة مـركـز سلامـة الــدواء häma

To:

SO/1, Pharmacy Department, the Medical City for Military and Security Services Director of Pharmaceutical Care, Royal Hospital Director of Pharmaceutical Care, Khoula Hospital Pharmacist Incharge, Al Nahda Hospital Grward Director of Pharmaceutical Care, DGHS, Muscat Governorate Director of Pharmaceutical Care, DGHS, AI Dakhliya Governroate Director of Pharmaceutical Care, DGHS, South Batinah Governorate Director of Pharmaceutical Care, DGHS, North Batinah Governorate Director of Pharmaceutical Care, DGHS, AI Dhahira Governorate Director of Pharmaceutical Care, DGHS, North Sharqiya Governorate Director of Pharmaceutical Care, DGHS, South Sharqiya Governorate Director of Pharmaceutical Care, DGHS, Musandam Governorate Director of Pharmaceutical Care, DGHS, Dhofar Governorate Director of Pharmaceutical Care, DGHS, Al Wusta Governorate Director of Pharmaceutical Care, DGHS, Buraimi Governorate **Director of Pharmaceutical Care, DGMS** Pharmacist Incharge, Al Massarah Hospital HOD, Pharmacy Department, Sultan Qaboos University Hospital Pharmacist Incharge, The Sultan's Special Force Pharmacist Incharge, Petroleum Development of Oman Pharmacist Incharge, LNG Oman

After Compliments,

Please find attached our Circular No <u>165/2025</u> dated <u>3/July/2025</u> regarding Risk of Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) Associated with Semaglutide.

Copy to:

- Director General, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Director Medical Device Control, DSC
- Supdt. of Central Drug Information
- Head of Cordn. & FU







ص.ب: ۳۹۳ مسقط - الرمز البريدي: ۱۰۰ - هاتف: ۲۲۳۰۷۱۱۱ - فاکس: P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489 OSCPHO Email: dscpho@moh.gov.om



Drug Safety Update

Subject: Risk of Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) Associated with Semaglutide.

The Drug Safety Center (DSC) would like to inform you that the World Health Organization (WHO) has issued a safety alert to inform healthcare professionals and regulatory authorities on the risk of non-arteritis anterior ischemic optic neuropathy (NAION) associated with the use of Semaglutide-containing medicines. The European Medicines Agency (EMA) has recommended updating the medicine information for this medicine to include NAION as a side effect, classified as very rare in frequency.

Semaglutide, a glucagon-like peptide-1 receptor agonist (GLP-1RA), is the active ingredient in medications used to treat type 2 diabetes and obesity.

NAION is a leading cause of vision loss in adults and the second most common optic neuropathy after glaucoma. It typically presents as sudden, painless, monocular vision loss accompanied by optic disc edema. The vision loss is generally irreversible, and there is currently no effective treatment available

Following a review of clinical trial data, post-marketing surveillance, and published medical literature, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has concluded that NAION should be listed as a very rare adverse event, occurring in approximately 1 in 10,000 users.

If patients experience a sudden loss of vision or rapidly worsening eyesight during treatment with semaglutide, they should contact their doctor without delay. If NAION is confirmed, treatment with semaglutide should be stopped.

Call to report:

Semaglutide is registered in Oman, healthcare professionals, patients, and earegivers are requested to submit adverse drug reaction reports to the pharmacovigitance & Drug Information department in the DSC.

PH. IBRAHIM NASSER AL RAS DIRECTOR GENERAL







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