SAFETY ALERT

DRAP SAFTEY ALERT NO. 65

Safety Alert of Risk of Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) with Semaglutide

Date: 6th of February, 2026

Target Audience.

- Provincial Health Departments/Provincial PV Centres;
- Manufacturers and importers of Semaglutide;
- Healthcare Professionals; and
- Patients.

Background.

The PRAC of the EMA on 6th of June, 2025, announced that it has concluded its review of medicines containing semaglutide following concerns regarding a possible increased risk of developing non-arteritic anterior ischemic optic neuropathy (NAION). Accordingly, the PRAC recommended updating the product information for semaglutide (Ozempic®, Rybelsus® and Wegovy®) to include the risk of non-arteritic anterior ischemic optic neuropathy (NAION) with a frequency of 'very rare' (meaning it may affect up to 1 in 10,000 people taking semaglutide). NAION is an eye condition that may cause loss of vision.

Results from several large epidemiological studies (for example, article 1 and article 2) suggest that exposure to semaglutide in adults with type 2 diabetes is associated with an approximately two-fold increase in the risk of developing NAION compared with people not taking the medicine. This corresponds to approximately one additional case of NAION per 10,000 person-years of treatment. Data from clinical trials also point to a slightly higher risk of developing the condition in people taking semaglutide, compared with people taking a placebo. 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.

Subsequently, the WHO on 27th of June 2025, has also issued an alert to healthcare professionals and regulatory authorities about the risk of non-arteritic anterior ischemic optic neuropathy (NAION) associated with the use of semaglutide medicines, following the recommendation by EMA-PRAC. At its May 2025 meeting, the WHO Advisory Committee on Safety of Medicinal Products (ACSoMP) also evaluated the evidence and concluded that the Risk Management Plan for semaglutide should be revised to include NAION as a potential risk, including any required additional pharmacovigilance activities. WHO is issuing this safety alert due to the widespread

global use of semaglutide and the serious nature of NAION. Furthermore, the WHO has received individual case safety reports (ICSRs) of NAION following semaglutide administration from multiple countries through VigiBase, the global database of reported adverse events of medicinal products.

Action in Pakistan.

The case was discussed in the 6th meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) held on 31st of December, 2025 which decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 that registration holders are required to include the risk of non-arteritic anterior ischemic optic neuropathy (NAION) in the Warnings and Precautions section and list it with a frequency of "very rare" in the Adverse Drug Reactions (ADRs) section of the SmPC/label of semaglutide-containing medicines registered in Pakistan, in line with the decisions of EMA-PRAC and WHO.

Therapeutic Goods Affected.

Name: Semaglutide is a GLP-1 (glucagon-like peptide-1) receptor agonist and is indicated for the treatment of diabetes and obesity. Semaglutide acts in the same way as GLP-1 (a natural hormone in the body) by increasing the amount of insulin that the pancreas releases in response to food. This helps with the control of blood glucose levels. Semaglutide also regulates appetite by increasing a person's feelings of fullness, while reducing their food intake, hunger and cravings.

Advice for Healthcare Professionals.

Healthcare professionals are informed that there is a "*very rare*' risk of non-arteritic anterior ischemic optic neuropathy (NAION) associated with the use of Semaglutide medicines in patients. If NAION is confirmed, treatment with Semaglutide should be stopped. It may affect up to 1 in 10,000 people taking semaglutide. NAION is an eye condition that may cause loss of vision. Healthcare professionals should be vigilant in patients with pre-existing optic nerve disorders or vascular risk factors.

Advice for patients.

If patients experience a sudden loss of vision or rapidly worsening eyesight during treatment with Semaglutide, they should contact their doctor without delay.

Guidelines for reporting Adverse Drug Reactions (ADRs).

Healthcare professionals and patients are requested to report any adverse drug reaction/event with the Semaglutide and/or any other medicine to the National Pharmacovigilance Centre (NPC), Drug Regulatory Authority of Pakistan (DRAP), through the Med Vigilance E-Reporting System (E-forms) available on the DRAP website. Similarly, adverse events and adverse drug reactions can also be reported through the VigiMobile App by scanning the following QR code, which can also be downloaded (add to home screen) in the mobile:

References.

- Minutes of the 6th meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC), DRAP.
- WHO Medical Product Alert: The use of semaglutide medicines and risk of non-arteritic anterior ischemic optic neuropathy (NAION)
- EMA-PRAC: conclusion of eye condition NAION as a very rare side effect of semaglutide medicines Ozempic, Rybelsus and Wegovy