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Direct healthcare-professional communication (DHPC)

Semaglutide products (Wegovy®, Ozempic® and Rybelsus®): a recommendation to minimize the risk of Non-arteritic Anterior Ischemic Optic Neuropathy (NAION).

Dear Healthcare professional,

In agreement with Saudi Food and Drug Authority (SFDA), Novo Nordisk A/S would like to inform you of the following:

The local Saudi Arabian product information for Novo Nordisk semaglutide products (Wegovy®, Ozempic® and Rybelsus®) will be updated with safety information regarding Non-arteritic Anterior Ischaemic Optic Neuropathy (NAION).

Summary

- Epidemiological studies have reported a potential association between semaglutide use and NAION.
- NAION is a very rare medical condition that affects the optic nerve, leading to sudden and often painless vision loss.
- NAION may lead to permanent visual impairment and requires urgent medical evaluation.
- Urgent ophthalmological assessment is required if visual symptoms occur.
- Discontinue semaglutide if NAION is confirmed.

Therapeutic indications for semaglutide products (Ozempic®, Rybelsus® and Wegovy®)

- Ozempic® is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise[1]
    - to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.[1]
    - to reduce the risk of sustained eGFR decline, kidney failure including initiation of chronic renal replacement therapy, or death from kidney failure or cardiovascular disease in adults with type 2 diabetes and chronic kidney disease.[1]

- Rybelsus® is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus[2]
    - to improve glycemic control as an adjunct to diet and exercise.[2]
    - to reduce the risk of major cardiovascular events such as heart attack, stroke or death in adults with type 2 diabetes mellitus with known heart disease and/or chronic kidney disease.[2]

- Wegovy® is indicated as an adjunct to a reduced-calorie diet and increased physical activity:
    - for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of ≥30 kg/m2(obesity), or ≥27 kg/m2 to <30 kg/m2 (overweight) in the

presence of at least one weight-related comorbidity e.g. dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease.[3]

- for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) in adult with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).[3]
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight.[3]
- Wegovy® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adolescents ages 12 years and above with obesity and body weight above 60 kg.[3]

Further information on Non-arteritic Anterior Ischaemic Optic Neuropathy (NAION) and recommended actions

NAION is a rare medical condition that affects the optic nerve, leading to sudden and often painless vision loss. The severity of the vision loss and the degree of optic nerve injury at presentation determine the prognosis of NAION[4]. In adults over 50 years of age, it is one of the most common causes for optic nerve swelling and optic neuropathy[4]. The exact pathogenesis of NAION has not been elucidated, but it is thought to be caused by hypoperfusion of the arteries supplying the optic nerve head[5]. Type 2 diabetes mellitus (T2D) and obesity are known risk factors for NAION[6,7]. Other risk factors include hypertension, hypertriglyceridemia, obstructive sleep apnoea and hypercholesterolemia, which are also known co-morbidities in people with T2D and obesity. There is therefore an overlap of the patient group at risk for NAION, and the patient group treated with glucagon-like peptide-1 receptor agonists (GLP-1 RAs), including semaglutide. Local risk factors may include tight optic disc, especially in the presence of disc drusen (disc at risk)[8].

Novo Nordisk A/S has evaluated all current available data sources for NAION with respect to semaglutide products, which included non-clinical studies, clinical studies, scientific literature and post-marketing. No plausible mechanism of action has been identified linking semaglutide to NAION. Data from randomised placebo-controlled trials of semaglutide and liraglutide including 96,829 participants and more than 205,000 participant-years of observation did not show an increased incidence of NAION in participants receiving GLP-1RA treatment versus placebo and, thus, do not suggest a relationship between GLP-1RA use and NAION.[9]

A causal relationship between semaglutide and NAION has not been established.

Recommendations for risk minimisation

- Inform patients about symptoms of NAION:
    - Sudden vision loss
    - Blurred or reduced vision
    - Visual field defects.
- Consider patient risk factors (e.g., T2D, hypertension, hyperlipidaemia, obstructive sleep apnoea).
- If visual symptoms occur: Urgently refer for ophthalmological assessment. Stop semaglutide treatment if NAION is diagnosed.

- Advise patient to seek urgent medical attention if they experience sudden vision changes and not to restart treatment unless advised by a physician.

Call for reporting

Adverse events can be reported through the channels listed below:

National Pharmacovigilance Center (NPC) - Saudi Food and Drug Authority (SFDA)

- SFDA call center: 19999
- E-mail: npc.drug@sfda.gov.sa
- Website: http://ade.sfda.gov.sa/

Novo Nordisk Saudi Arabia

- E-mail: nngulfsafety@novonordisk.com
- Website: https://www.novonordisk.com.sa/

Company contact point

Further information can be obtained by contacting nngulfsafety@novonordisk.com

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