PRAC concludes eye condition NAION is a very rare side effect of semaglutide medicines

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Information on Semaglutide

- Semaglutide, a GLP-1 receptor agonist, is the active substance in certain medicines used in the treatment of diabetes and obesity (namely Ozempic, Rybelsus and Wegovy).
- 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.

In Malta the following products are authorised through various licensing procedures

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
Semaglutide 0.25mg	Ozempic 0.25mg	1 x 1.5ml pen and 4 disposable needles	POM	EU/1/17/1251/002	Novo Nordisk S.p.A
Semaglutide 0.5mg	Ozempic 0.5mg	1 x 1.5ml pen and 4 disposable needles	POM	EU/1/17/1251/003	Novo Nordisk S.p.A
Semaglutide 1mg	Ozempic 1mg	1 x 1.5ml pen and 4 disposable needles	POM	EU/1/17/1251/005	Novo Nordisk S.p.A

Information from the EMA about the safety concern

- EMA's safety committee, the Pharmacovigilance Risk Assessment Committee (PRAC), has concluded its review of medicines containing semaglutide following concerns regarding a possible increased risk of developing non-arteritic anterior ischemic optic neuropathy (NAION), an eye condition that may cause loss of vision. Semaglutide, a GLP-1 receptor agonist, is the active substance in certain medicines used in the treatment of diabetes and obesity.

- After reviewing all available data on NAION with semaglutide, including data from non-clinical studies, clinical trials, post-marketing surveillance and the medical literature, PRAC has concluded that NAION is a very rare side effect of semaglutide (meaning it may affect up to 1 in 10,000 people taking semaglutide).

- Results from several large epidemiological studies 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; one person-year corresponds to one person taking semaglutide for one year. Data from clinical trials also point to a slightly higher risk of developing the condition in people taking semaglutide, compared with people taking placebo (a dummy treatment).

- EMA has therefore recommended that the product information for semaglutide medicines is updated to include NAION as a side effect with a frequency of 'very rare'.

- The potential association between exposure to semaglutide and NAION (non-arteritic anterior ischemic optic neuropathy) was evaluated as part of a post-authorisation measure (LEG) resulting from a PSUR assessment.
- The PRAC recommendations will now be sent to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States in due course.

In Malta

For Healthcare Professionals

- If NAION is confirmed, treatment with semaglutide should be stopped.
- Product information for semaglutide is available on the EMA website (refer to Ozempic, Rybelsus and Wegovy)

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.

For more information please see the European Medicines Agency's press release

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on semaglutide. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines

Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate
Malta Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Malta Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Malta Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Malta Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

Feedback:

We thank you for your interest and look forward to hearing your opinion.

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Pharmacovigilance Section

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San Ġwann SĠN 3000

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