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(IN REPLY PLEASE QUOTE THIS FILE REF.)

9 Jun 2025

Dear Healthcare Professionals,

European Union: PRAC concludes eye condition NAION is a very rare side effect of semaglutide medicines Ozempic, Rybelsus and Wegovy

Your attention is drawn to the European Medicines Agency's (EMA) announcement that its safety committee, 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 (namely Ozempic, Rybelsus and Wegovy).

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'. 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.

More about the medicines

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.

More about the procedure

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 review has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which has made a set of recommendations.

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.

Please refer to the following website in EMA for details:
https://www.ema.europa.eu/en/news/prac-concludes-eye-condition-naion-very-rare-side-effect-semaglutide-medicines-ozempic-rybelsus-wegovy

In Hong Kong, there are 11 registered pharmaceutical products containing semaglutide. All products are prescription-only medicines. So far, the Department of Health (DH) has received 10 cases of adverse drug reaction related to semaglutide, but these cases are not related to NAION. Related news was previously issued by the EMA, and was posted on the Drug Office website on 18 January 2025. In light of the above EMA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please

refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

pp. (Vincent CHIANG)

for Assistant Director (Drug)