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

Treatment with semaglutide should be stopped if NAION occurs

EMA's safety 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

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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.