

semaglutide 3mg, 7mg and 14mg tablets (Rybelsus®)

Novo Nordisk

10 July 2020 (*Issued 07 August 2020*)

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following assessment under the abbreviated process

semaglutide (Rybelsus®) is accepted for restricted use within NHSScotland.

Indication under review: for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise

- As monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- In combination with other medicinal products for the treatment of diabetes.

SMC restriction: In addition to other oral anti-diabetic medicines, or as an add-on to basal insulin, as an alternative glucagon-like peptide-1 receptor agonist option.

SMC has previously accepted semaglutide solution for subcutaneous injection (Ozempic®) for restricted use (SMC2092). Oral semaglutide (Rybelsus®) costs the same per day as subcutaneous semaglutide (Ozempic®). Prescribers should note that the effect of switching between oral and subcutaneous semaglutide cannot easily be predicted because of high pharmacokinetic variability of oral semaglutide. Clinical effectiveness should be considered when making switching decisions between formulations.

The company's submission related only to use in addition to other medicinal products for the treatment of diabetes, therefore SMC cannot recommend semaglutide tablets as monotherapy.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 29 June 2020.

**Chairman
Scottish Medicines Consortium**