Prescribing Update

NHS Lancashire and South Cumbria Integrated Care Board

Medicines Matters

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Rybelsus® (oral semaglutide): risk of medication error due to introduction of new formulation with increased bioavailability.

In September 2025 all practices received a Direct Healthcare Professional Communication from Novo Nordisk regarding a change to the formulation of Rybelsus (oral semaglutide). At that time the EMIS clinical system had not been adequately updated to allow practices to prescribe the new formulations and we advised practices to refrain from switching patients over until further notice. **Over the last few weeks these updates to the EMIS system have been implemented and supplies of the new formulations have now started to make their way into distribution chains.**

Novo Nordisk is replacing the initial formulation (3 mg, 7 mg, 14 mg tablets) of Rybelsus with the new formulation (1.5 mg, 4 mg, 9 mg tablets). Healthcare professionals should be aware that the original formulation is anticipated to be available until approximately 31st January 2026 however, original formulation stock of imported Rybelsus ® may be within supply chains beyond this date.

There is a risk of patient harm arising through medication error during the transition period where the original and new formulation of Rybelsus ® tablets, which have different stated mg doses but are bioequivalent, will both be available on the market. Medication error may result in overdose if healthcare professionals prescribe more than one tablet per day of the new formulation to try to match the dose to the old strengths. This could affect disease control and increase the risk of side effects e.g. nausea, vomiting and diarrhoea.

Please find the link here for further **advice for Healthcare professionals from the MHRA**

- The new formulation of Rybelsus ® has **increased** bioavailability therefore lower strength tablets achieve the same drug exposure and clinical effect as the previous formulation.
- The Product Information has been updated to explain the difference between the two formulations and enable readers to identify the equivalent doses across formulations with bioequivalent doses.
- Details of the new formulation can also be found in the Direct Healthcare Professional Communication distributed by the Marketing Authorisation Holder in September 2025.
- **Rybelsus tablets have been replaced with a new formulation with increased bioavailability, which is bioequivalent to the initial formulation as described in the table below:**

Initial formulation (one oval tablet)	Bioequivalent	New formulation (one round tablet)
3 mg (starting dose)	**=**	**1.5 mg (starting dose)**
7 mg (maintenance dose)	**=**	**4 mg (maintenance dose)**
14 mg (maintenance dose)	**=**	**9 mg (maintenance dose)**

- **Rybelsus ® should always be taken as ONE tablet per day.** Taking more than this will result in overdosing, which affects disease control and increases the risk of adverse events.
- Prescribe patients starting Rybelsus ® treatment the new formulation once it is available in your prescribing system.
- Systematically switch patients who are currently on Rybelsus ® to the new formulation once it is available in your prescribing systems.
- Inform patients about the change in formulation and strength when the new formulation is prescribed or dispensed. Refer patients to the patient transition guide for further information.
- Ensure that patients are aware that tablets with the new formulation and lower strengths will have the same effects as the tablets with the initial formulation and higher strengths.
- Document in the patient's notes that the change has been undertaken and communicate to other parts of the system where required.
- Report medication errors or near misses via local risk management systems and medication errors resulting in patient harm on the Yellow Card website