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Rybelsus: Risk of medication error due to new tablet formulation

There is a risk of medication errors with the diabetes medicine Rybelsus (semaglutide) due a change in the medicine's formulation.

The new formulation of Rybelsus tablets has higher bioavailability (the proportion of the active substance absorbed into the blood stream) than the initial formulation, which means that lower doses are needed to achieve the same effect. The new formulation has the same effectiveness and safety as the initial formulation and is taken in the same way.

As tablets of both formulations will temporarily be available on the market, there is a risk of taking the wrong dose. This could result in overdosing, increasing the risk of gastrointestinal side effects (side effects affecting the stomach and the gut).

The company has changed the tablet size and shape, as well as the packaging for the new formulation. A letter will be sent to healthcare professionals to alert them to the changes and the need to inform patients of the change in formulation and dose.

More information is available below.

Information for patients

- The formulation of the diabetes medicine Rybelsus (semaglutide) is being changed to one which is better absorbed into the blood stream. As a result, the new tablets will contain a lower dose of Rybelsus, but will be just as effective as the initial formulation.
- The colour of your packaging will stay the same (i.e., green, red or blue) and you will still need to take only one Rybelsus tablet each day.
- If you are currently using Rybelsus, your doctor or pharmacist will inform you about the change and tell you which dose of the new formulation you should use.
- The new Rybelsus tablets will be smaller and have a different (round) shape. The outer carton and the blister strips will be smaller, and the blister strips will be silver on both sides (see pictures below).

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- Complete information on your medicine and how to use it is provided in the package leaflet, which can be found in your box of tablets. The package leaflet is also available on EMA's website in all EU languages.
- If you have any questions about your treatment and when the new formulation will be available in your country, contact your doctor, pharmacist or nurse.

Information for healthcare professionals

- Rybelsus (semaglutide) tablets (3 mg, 7 mg and 14 mg) are being replaced with a new formulation with increased bioavailability, which will contain a lower dose of semaglutide (1.5 mg, 4 mg and 9 mg). The table below shows the corresponding replacement dose for each strength of the old formulation:

Initial formulation (one oval tablet)		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)**

- The colour of the different dosing steps has been retained, but the new formulation has a different tablet size and shape. In addition, the outer carton and the blister strips will be smaller, and the blisters will be silver on both the front and the back (see figure below).
- The two formulations will temporarily co-exist on the market to ensure continued availability of the medicine.
- To avoid medication errors, healthcare professionals should inform patients currently taking Rybelsus about the change in formulation and dose when they prescribe or dispense the new Rybelsus formulation. Patients must also be reminded that their Rybelsus dose should always be taken as one tablet a day.
- Healthcare professionals should prescribe the new formulation doses for patients who are starting Rybelsus for the first time.

A direct healthcare professional communication (DHPC) will be sent to healthcare professionals prescribing, dispensing or administering the medicine. The DHPC will also be published on a dedicated page on the EMA website.

<table>
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<td>Tablet size: Tablets for the new formulation are smaller in size and have a different shape (round). Tablets are debossed with the strength.</td>
<td>Initial New
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<tr>
<td>Primary packaging: New formulation blisters are silver both on the front and back and are smaller compared to blisters with the initial formulation</td>
<td>Initial formulation
 

New formulation
 
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More about the medicine

Rybelsus is a medicine used to control blood glucose (sugar) levels in adults whose type 2 diabetes is not controlled well enough. Rybelsus contains the active substance semaglutide.

More information about Rybelsus can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/EPAR/rybelsus.