

## Safety Alert

11-2023

### Rybelsus

EDA performs label update to include the following:

#### 2. What you need to know before you take Rybelsus®

##### Stomach and gut problems and **dehydration**

During treatment with this medicine, you may feel sick (nausea) or be sick (vomiting), or have diarrhoea. These side effects can cause dehydration (loss of fluids). It is important that you drink enough fluids to prevent dehydration. This is especially important if you have kidney problems. Talk to your doctor if you have any questions or concerns.

#### 4. Possible side effects

**Uncommon** (may affect up to 1 in 100 people)

- **allergic reactions like rash, itching or hives.**

#### **Background:**

Rybelsus is indicated 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.

#### **References:**

EMA:

[https://www.ema.europa.eu/en/documents/product-information/rybelsus-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/rybelsus-epar-product-information_en.pdf)