21 August 2025

Evrysdi 0.75 mg/mL powder for oral solution (risdiplam): omission of mandatory labelling statement in the EU product label and summary of product characteristics

Dear Healthcare Professional,

Roche, in agreement with the European Medicines Agency and the <National Competent Authority> would like to inform you of the following:

Summary

- **A mandatory labelling statement has been mistakenly omitted from the EU product label and summary of product characteristics (SmPC) for Evrysdi 0.75mg/mL powder for oral solution.**

- **The statement "*Do not store above 25°C*" is missing from section "6.4 Special precautions for storage" (within the powder for oral solution sub-section) of the SmPC, product carton and bottle labels, and the Instruction for Constitution. The package leaflet is not impacted, as the patients only receive the constituted oral solution, and the proper storage condition for the constituted oral solution is already included in the package leaflet.**

- **Pharmacists must not dispense Evrysdi 0.75 mg/mL powder for oral solution if the storage temperature of the unconstituted powder has exceeded 40°C / 75% RH (relative humidity) for 3 months, or 30°C / 75% RH for 12 months because the impact of storing outside of these conditions has not been studied.**

- **Follow the local country process to submit a product complaint 24/7 and to receive advice about replacement and ensuring continued dosing.** <include the details (e.g. name, postal address, fax number, website address) on how to access the affiliate product complaint>.

Background

Evrysdi (risdiplam) is indicated for the treatment of 5q spinal muscular atrophy (SMA) in patients with a clinical diagnosis of SMA Type 1, Type 2 or Type 3 or with one to four SMN2 copies. Evrysdi powder for oral solution must be constituted with purified water or water for injection by a healthcare professional (e.g. pharmacist) prior to being dispensed.

On May 21, 2025, a misalignment was identified between the approved product labelling statement and the storage conditions in Roche's internal labelling statement database for Evrysdi when it is stored as a powder (not after it is constituted with water). The internal database, regarding the unconstituted powder, states "do not store above 25°C," while the documentation for the marketing authorisation and actual product labelling for EU/EEA countries does not include this temperature-specific storage statement. This issue affects all EU/EEA countries.

Testing indicates that Evrysdi in the powder form is stable at 25°C / 60% RH (relative humidity) during the full shelf-life of the product. All available stability data collected at 40°C / 75% RH for 3 months, at 30°C / 75% RH for 12 months, and 25°C / 60% RH (full shelf life) demonstrate that Evrysdi in the powder state remains within specifications under these conditions, allowing for temperature excursions of up to 30°C or even 40°C for several months. A decrease in risdiplam content was observed at 40°C / 75% RH over 6 months with the content found to be at 94.7% (limit: 95.0%). This lowered content is not expected to cause concerns with potential underdosing.

Transport of the medicinal product to local wholesalers or pharmacies is maintained at 2 - 25°C.

Based on the stability data mentioned above, an impact on patient safety is not expected, if Evrysdi is stored within these parameters.

Corrective and Preventive Actions

The EU SmPC, labelling and instruction for constitution will be updated with the relevant storage conditions for the powder form of Evrysdi. The label update will be expedited. Corrective and preventive actions have been defined to rectify the situation as soon as possible and to prevent similar events from recurring.

Pharmacists should:

- not dispense Evrysdi 0.75mg/ mL Powder for Oral Solution if the storage temperature of the powder exceeded 40°C/ 75% RH for 3 months, or 30°C / 75% RH for 12 months.
- follow the local country process to submit a product complaint 24/7 and to receive advice about replacement and ensuring continued dosing.

Call for reporting

Healthcare professionals are asked to report any suspected adverse drug reactions in accordance with the national spontaneous reporting system and include batch/Lot number if available; <include the details (e.g. name, postal address, fax number, website address) on how to access the national reporting system>.

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>