



## Important Information

### Direct Healthcare Professional Communication (DHPC)

12 June 2026

#### **Evrysdi (risdiplam) 0.75 mg/mL powder for oral solution (PfOS), EU/1/21/1531/001**

Dear Pharmacist,

Roche, in agreement with the European Medicines Agency and the Health Products Regulatory Authority (HPRA), would like to inform you of the following:

#### **Summary**

- **Complaints were reported from a pharmacy in Germany regarding insoluble foreign particles in constituted Evrysdi® 0.75 mg/mL oral solution for Batches B2033B03 and B2035B09.**  
The potential presence of particles in additional batches cannot be excluded. This includes finished-product batches labeled with batch numbers starting with one of the following numbers: B2033, B2034, B2035, B2036, B2037, B2038 and B2039. No additional batches are in scope. (Batches B2034B10, B2036B15 and B2039B17 have been supplied to the IE market).
- **Investigations of the MAH have shown that these particles consist of white Polytetrafluorethylene (PTFE-Teflon). PTFE is a chemically inert, non-toxic material that is expected to pass through the gastrointestinal tract unchanged without systemic absorption. Based on the identification of PTFE particles measuring 0.3 mm to 2.7mm, the clinical risk to the patient population is considered low as the presence of these small particles does not pose a specific or heightened risk to patients with SMA when compared to the general risk associated with the administration of liquids or food.**
- **None of the complaints received in this context were associated with adverse events.**
- **A review of relevant post-marketing spontaneous adverse event reporting data shows no evidence of safety signals causally related to this product complaint. The events reported in the review were typical for this patient population and consistent with underlying disease progression.**
- **A review of the company safety database during the reporting interval following the release of the batches in scope and routine signal management identified no new signals regarding gastrointestinal obstruction, respiratory distress, respiratory failure or mortality.**



## **Background on the safety concern**

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. A pharmacy in Germany identified foreign particles upon constituting the solution.

The identified particles consist of a chemically inert, non-toxic material that is expected to pass through the gastrointestinal tract unchanged without systemic absorption.

During SMA disease progression, dysphagia is a well-known potential condition which may present critical risks to patients. Dysphagia is traditionally managed proactively through the insertion of a feeding tube to ensure safe nutrition and reduce respiratory risks. In such a setting, the occasional presence of particulate matter should not increase the inherent risk to patients beyond the existing risks of administration of liquids or food.

## **Corrective and Preventive Actions**

The MAH, in collaboration with the HPRA, would like to provide Pharmacists with instructions with additional precautionary measures:

1. Pharmacists should check whether the solution in the bottle is clear, as per the *Instruction for constitution* step 5, or if it contains visible insoluble foreign particles after constitution of the solution. The amber colored glass bottle and the clarity of the constituted drug product solution allow the detection of the relevant white PTFE particles under normal ambient light with the bare eye.
2. The unit should not be dispensed if visible foreign particles are identified in the bottle after shaking the constituted product for 15 seconds two times, as per the *Instructions for constitution*. Instead, the unit should be replaced by a new, unaffected bottle promptly to ensure treatment continuity.

Product complaints can be directed 24/7 to Ireland Quality at Roche Products (Ireland) Limited by email (ireland.quality.iq1@roche.com) or telephone 01-4690700.

## **Call for reporting**

Pharmacists are asked to report any suspected adverse drug reactions via HPRA Pharmacovigilance, website: [www.hpra.ie](http://www.hpra.ie) and include batch/Lot number if available.

## **Company contact point**

Should you have any questions regarding the use of Evrysdi 0.75 mg/mL powder for oral solution (risdiplam) please contact us at: Medical Information at Roche Products (Ireland) Limited by telephone (01 4690700) or email ([Ireland.druginfo@roche.com](mailto:Ireland.druginfo@roche.com)).

Evrysdi 0.75 mg/mL powder for oral solution Summary of Product Characteristics (SmPC) is available on [www.medicines.ie](http://www.medicines.ie).

Yours sincerely,

Signed by:  
  
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Signing Reason: I approve this document  
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