Direct Healthcare Professional Communication

November 2026

Evrysdi® (risdiplam) 0.75 mg/mL powder for oral solution regarding insoluble foreign particles white Polytetrafluorethylene (PTFE-Teflon) (PfOS)

Dear Healthcare Professional,
Roche Egypt in agreement with the General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at the Egyptian Drug Authority 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.**
- **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 is ongoing. Routine signal management identified no new signals regarding gastrointestinal obstruction, respiratory distress, respiratory failure or mortality.**

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. A pharmacy in Germany has 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.
- Yet, the MAH, in collaboration with relevant Health Authorities, would like to provide Pharmacists with instructions with additional precautionary measures

Corrective and Preventive Actions

As a precautionary measure, pharmacists should:

- Check whether the solution in the bottle is clear as per the Instruction for constitution step 5 or 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.
- Do not dispense Evrysdi 0.75 mg/mL Powder for Oral Solution 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.
- Replace the affected medication by a new, unaffected bottle promptly in order to ensure treatment continuity.

References

1. Germany (bfarm.de): https://www.bfarm.de/SharedDocs/Risikoinformationen/Pharmakovigilanz/DE/RHB/2026/rhb-evrysdi.pdf?__blob=publicationFile
2. Switzerland (Swissmedic): https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/market-surveillance/health-professional-communication--hpc-/dhpc-evrysdi-risdiplamum.html

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt,

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://vigiflow-eforms.who-umc.org/eg/med

QR Code:

Hotline: 15301