27.5.2026

Evrysdi (risdiplam) 0.75 mg/mL powder for oral solution (PfOS)

Dear Prof. D. Pace,

CPSU, in agreement with the European Medicines Agency and the Malta Medicines 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 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 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.
- Product complaints can be directed 24/7 to [MAH contact point email address + telephone number].

Call for reporting

Pharmacists are asked to report any suspected adverse drug reactions in accordance with the national spontaneous reporting system and include batch/Lot number if available;

Bernardette Rossi - Central Procurement and Supplies Unit (CPSU); UB002 San Gwann Industrial Estate, San Gwann - SGN3000, Malta

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Malta Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to;
P: Pharmacovigilance Section at Post-Licensing Directorate, Malta Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000
E: postlicensing.medicinesauthority@gov.mt

Company contact point

Bernardette Rossi - Central Procurement and Supplies Unit (CPSU); UB002 San Gwann Industrial Estate, San Gwann - SGN3000, Malta
Yours sincerely,

Bernardette Rossi
Professional Practice Pharmacist