Wichtige Sicherheitsinformation
in Absprache mit swissmedic

Address

Basel, May 2026

Important drug safety notification
Evrysdi®(risdiplam) 0.75 mg/mL powder for oral solution: Information and precautions

Dear Sir or Madam,

Roche Pharma (Switzerland) AG, in agreement with Swissmedic, 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.**
- **The potential presence of particles in additional batches cannot be excluded. The following batches sold in Switzerland may also be affected: B2033B05, B2034B14, B2037B12 and B2038B25. No additional batches are in scope.**
- **Investigations of the MAH have shown that these particles consist of white polytetrafluoroethylene (PTFE-Teflon). PTFE is a chemically inert, 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 2.7 mm, 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.**

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- **None of the complaints received in this context were associated with adverse events.**
- **A review of relevant post-marketing spontaneous adverse event reporting data showed 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 safety signals regarding gastrointestinal obstruction, respiratory distress, respiratory failure or mortality.**

Background information

Evrysdi® (risdiplam) is indicated for the treatment of 5q spinal muscular atrophy (SMA) in paediatric and adult patients. 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, 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.
Nevertheless, the MAH, in collaboration with relevant Health Authorities, would like to provide pharmacists with instructions with additional precautionary measures.

Measures and instructions/recommendations for healthcare professionals

Healthcare professionals should take the following precautionary measures:

- *Check whether the solution in the bottle is clear after constitution (as per the Instructions for constitution, Step 5) or contains visible insoluble foreign particles.*
- *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.*

- *If any particles are discovered in a reconstituted solution, please report this product complaint to Roche Pharma Switzerland AG (Quality Assurance Department: basel.rpsqadra@roche.com).*
- *Remind patients, parents and caregivers of the instructions for administration contained in the relevant approved Product Information that requires visual inspection of the syringe content for the presence of bubbles prior to administration. If foreign floating particles are detected in the syringe, the product shouldn't be used.*

Reporting adverse reactions

Swissmedic recommends the use of the notification portal, Electronic Vigilance System (ElViS), developed for reporting adverse drug reactions (ADRs). All required information can be found at www.swissmedic.ch.

Contact details

If you have questions or need additional information about the use of the product, please contact swiss.medinfo@roche.com (+ 41 61 715 42 33 / + 41 61 715 42 44).

Yours faithfully,

Roche Pharma (Switzerland) AG

Dr Matthias Schwebe
Head Quality Management / Responsible Person

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Patient Safety Group Lead

Appendices: none