

March 2021

Subject:

- **Information Regarding Potential Leakage of Evrysdi™ (risdiplam) 0.75 mg/mL NDC 50242-175-07 Solution from Bottles Delivered to Patients**
 - **Replacement of Leaking Bottles**
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Dear SMA patient or caregiver,

Genentech would like to inform you of reports received about leakage of Evrysdi constituted solution from bottles delivered to patients. This letter also provides instructions for inspecting your shipment and seeking replacement if a bottle you receive is leaking.

The leakage is not anticipated to impact the safety or efficacy of the administered drug, and patients can continue to take Evrysdi safely until they receive replacement.

Genentech is working in cooperation with the U.S. Consumer Product Safety Commission (CPSC) to inform consumers to inspect the bottles for leakage. Prescription drugs are required to be in properly functioning special packaging (child-resistant and senior-friendly packaging) under the Poison Prevention Packaging Act. Please see the information below to receive a replacement at no additional cost. The recall alert is available here:

<https://www.cpsc.gov/Recalls/2021/Genentech-Recalls-Prescription-Drug-Evrysdi-Due-to-Failure-to-Meet-Child-Resistant-Packaging-Requirements-Risk-of-Drug-Exposure-through-Eye-or-Skin-Absorption-Recall-Alert>

Requested Actions

Please follow the steps below to ensure safe handling and to request replacement for a leaking bottle at no additional cost:

- Upon receipt of a shipment carefully inspect each bottle for leakage.
- If you notice leakage on any bottle, dry off the bottle with a dry paper towel then rinse the closed bottle with water.
- Store the bottle out of sight and out of reach of children.
- Call Genentech Product Complaints at 1-800-334-0290 to coordinate your free replacement and further instructions.

Description of the Issue

Investigations into the root cause have shown that the fit between the Evrysdi bottleneck and the inserted Press in Bottle Adapter (PIBA) may lead to leakage under certain conditions. Genentech has informed the U.S. Food and Drug Administration (FDA) and CPSC, and implemented appropriate measures to reduce the risk during future shipments in agreement with those regulatory bodies.

Caregivers and those involved in preparing and administering Evrysdi, as well as those who might otherwise handle the bottle, may be at risk of drug exposure from getting Evrysdi on the skin. It is therefore important to follow the instructions in the Evrysdi Instructions for Use (IFU) leaflet carefully:

- Avoid getting Evrysdi on your skin or in your eyes. If Evrysdi gets on your skin, wash the area with soap and water. If Evrysdi gets in your eyes, rinse your eyes with water.
- If you spill Evrysdi, dry the area with a dry paper towel and then clean the area with water. Throw away the paper towel in the trash and wash your hands well with soap and water.
- Store EVRYSDI in the original amber bottle in an upright position with the cap tightly closed. Keep out of sight and out of reach of children to avoid accidental exposures.

Reporting Adverse Events and Packaging Issues

You may report any adverse events suspected to be associated with the use of Evrysdi to Genentech at 1-888-835-2555. Alternatively, this information may be reported to FDA's MedWatch reporting system by phone at 1-800-FDA-1088 or online (www.fda.gov/medwatch).

Other issues related to the packaging may be reported to CPSC's Safer Products (www.saferproducts.gov).

Your safety is our primary concern and we take product quality concerns very seriously. We would like to assure you that we are working diligently to resolve this issue. We apologize for any resulting inconveniences this may cause.

Sincerely,



Jamie Freedman MD, PhD
Head of US Medical Affairs