

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**
- 

Dear Healthcare Provider:

The purpose of this letter is to inform you of reports received about leakage of Evrysdi constituted solution from bottles delivered to patients. This letter also provides instructions for inspecting the shipment and seeking replacement if a bottle they 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 as clinically indicated.**

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>

**Prescriber Action**

Please advise patients and caregivers to 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 leakage is noticed on any bottle, dry off the bottle with a dry paper towel and 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 replacement and return of the leaking bottle.

Please also advise patients and caregivers to continue following the instructions in the Instructions for Use (IFU):

- 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 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.

### **Description of the Issue**

Evrysdi is indicated for the treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older. As you know, Evrysdi is prepared and constituted in a specialty pharmacy and shipped directly to patient's homes. Genentech has received some reports from patients and caregivers that bottles have leaked during shipment.

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.

While leakage is not anticipated to impact the safety and efficacy of the administered drug, 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.

More information on associated toxicities from drug exposure are provided in the full prescribing information. Please continue to refer your patient to the PPI (Patient Product Information) and IFU (Instructions for Use) for questions regarding the safe use of Evrysdi.

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.

The safety of patients and caregivers is the primary focus at Genentech. We are working diligently to resolve this issue and thank you for your collaboration.

### **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](http://www.fda.gov/medwatch)).

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

### **Company Contact Point**

Should you have any questions about the information in this letter or the safe and effective use of Evrysdi, please feel free to contact us at: Genentech Medical Information/Communications Department at 1-800-821-8590.

This letter is not intended as a complete description of the benefits and risks related to the use of Evrysdi. Please refer to the enclosed full prescribing information, PPI and IFU.

Sincerely,



Jamie Freedman MD, PhD  
Head of US Medical Affairs