PROJECT ALIVE

Clinical trial and FDA-reported adverse reactions

The FDA prescribing information reports that the **most common adverse reactions (≥20% of patients)** were:

- Infusion-associated reactions (most common)
- Upper respiratory tract infections
- Ear infections
- Fever
- Anemia
- Cough
- Vomiting
- Diarrhea
- Rash
- COVID-19
- Runny or congested nose
- Headache
- Hives (urticaria)
- Falls
- Skin abrasions

Infusion-associated reactions

These are the side effects clinicians are watching for most closely. They can occur during the infusion or within 24 hours afterward and may include:

- Chills
- Flushing
- Rash or hives
- Itching
- Fever
- Vomiting
- Diarrhea
- Abdominal pain
- Headache
- Cough
- Wheezing
- Low blood pressure
- Fast heart rate
- Swelling (angioedema)

Most reactions occurred **during the first 8 weeks of treatment** and became less frequent over time. Patients who were **ERT-naïve** experienced infusion reactions more often than those who had previously received Elaprase.

Serious reactions

The FDA includes a **boxed warning** for hypersensitivity reactions, including anaphylaxis. Because of this:

- Initial infusions must occur in a healthcare setting.
- Patients are monitored closely during and after treatment.
- Premedications (antihistamines, acetaminophen, and sometimes corticosteroids) are commonly used when appropriate.

The label also recommends monitoring for:

- **Anemia**
- **Membranous nephropathy (kidney disease)** through urine protein and kidney function testing.

What families have been reporting

Because Avlayah was only approved in **March 2026**, real-world experience is still limited. Early reports from clinicians and families have generally been consistent with the clinical trials:

- Most children tolerate infusions well after the initial dose-escalation period.
- Infusion reactions remain the most commonly discussed side effect.
- Many families report that reactions become less frequent as treatment continues, especially with individualized infusion rates and premedication when needed.

At this stage, there are **no widespread new safety signals** beyond what was observed during the clinical development program, but post-marketing monitoring is ongoing.