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Switching from Elaprase to Avlayah

Experiences After Switching

Publicly available real-world family reports remain limited because Avlayah was approved in March 2026. The strongest available evidence comes from the clinical trial, which included 32 children who had previously received another ERT, primarily Elaprase.

Among patients switching from prior ERT:

- Infusion-associated reactions were common, particularly during the early weeks.
- Reported symptoms included fever, rash, hives, flushing, vomiting, cough, diarrhea, headache, chills and irritability.
- Reactions generally became less frequent with continued treatment.
- Previously treated patients had fewer and generally less severe reactions than children who had little or no previous ERT exposure.
- Some patients required temporary infusion pauses, slower rates, additional medication or temporary dose reductions.
- A prior history of tolerating Elaprase does not guarantee that a child will tolerate Avlayah without a reaction because it is a different protein formulation and uses a substantially higher weight-based dose.

In the Avlayah trial, infusion-associated reactions occurred in 87% of all 47 patients. However, this included reactions of any severity over a median treatment exposure of more than two years. Three patients, or 6%, experienced severe reactions, one discontinued because of a reaction, and one experienced anaphylaxis. Reactions were most common during the first eight weeks, with the first reaction occurring at a median of approximately two weeks.

The early experience can therefore be summarized as: **switching patients may still experience new infusion reactions, but prior ERT exposure appears to reduce the likelihood and severity compared with starting Avlayah without previous ERT.**

Practical Steps for Infusion Teams

Avlayah has a structured dose-escalation schedule intended to improve tolerability:

- Weeks 1–4: 3 mg/kg weekly
- Weeks 5–8: 7.5 mg/kg weekly
- Week 9 onward: 15 mg/kg weekly

The dose should not be increased when the current level is not tolerated.

Infusion centers may also:

- Consider antihistamines, fever-reducing medications and/or corticosteroids before the infusion.
- Keep the initial infusions in a healthcare setting with emergency medications and cardiopulmonary-resuscitation equipment available.
- Observe closely during the first eight weeks and continue watching for delayed symptoms for at least 24 hours.
- Document the timing, symptoms, infusion rate, medications given and response to treatment after every reaction.
- Temporarily stop the infusion or reduce the rate by at least 50% for a mild or moderate reaction, then increase it gradually as tolerated.
- Reassess premedications, infusion rate and dose before the next treatment.
- Avoid escalating to the next dose level until the current dose is tolerated.
- Monitor children with cardiac or respiratory impairment especially closely.
- Discontinue the infusion and provide emergency treatment immediately for a severe reaction or suspected anaphylaxis.

Premedication can lower risk but does not completely prevent reactions. Delayed reactions occurring two or more hours after the infusion have also been reported.

Elaprase vs. Avlayah Infusion Reactions

Feature	Elaprase	Avlayah
Administration	Weekly IV infusion, 0.5 mg/kg	Weekly IV infusion, escalated to 15 mg/kg
Boxed warning	Anaphylaxis	Hypersensitivity reactions, including anaphylaxis

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Feature	Elaprase	Avlayah
Frequently reported reaction symptoms	Rash, hives, itching, flushing, fever, headache, vomiting and respiratory symptoms	Chills, swelling, low blood pressure, rapid heart rate, hives, vomiting, wheezing, fever, flushing, rash, cough, diarrhea, abdominal symptoms, headache and irritability
Timing	During infusion or up to 24 hours afterward; reactions may occur after long-term treatment	During infusion or within 24 hours; most common during the first eight weeks, but may occur later
Trial frequency	Hypersensitivity reactions occurred in approximately 53% of patients in the 24-month extension study and 57% of children age seven and younger	Infusion-associated reactions occurred in 87% of the 47-patient trial population
Severe reactions	Anaphylaxis and serious respiratory complications have occurred	Severe infusion reactions occurred in 6%; anaphylaxis occurred in 2%
Effect of previous ERT	Not applicable when initiating Elaprase	Reactions were more frequent in ERT-naïve patients than in patients switching from previous ERT
Typical management	Premedication, slowing or stopping the infusion and emergency treatment when necessary	Dose escalation, premedication, slowing or stopping the infusion, temporary dose reduction and emergency treatment when necessary

Elaprase hypersensitivity reactions were reported in approximately 53% of patients during its extension trial and 57% of younger children. Common reactions included fever, rash, vomiting and hives.

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Important Limitation

The percentages should **not be interpreted as proof that Avlayah is less tolerable than Elaprase**. The studies differed substantially in patient ages, definitions, treatment durations, dosing, monitoring and how reactions were recorded. The Avlayah label explicitly cautions against directly comparing adverse-event rates between different clinical trials.