

PATIENT INFORMATION

SS-31 (ELAMIPRETIDE)

Mitochondrial Cardiolipin Binder • Alchemy Compounding Pharmacy

IMPORTANT PRODUCT DISTINCTION This Alchemy compounded SS-31 pen is not the FDA-approved Forzinity formulation. Evidence and prescribing information for Forzinity are useful clinical context but cannot automatically be transferred to this compounded product.

What is SS-31?

SS-31 is the research name commonly used for elamipretide, a small mitochondria-targeting tetrapeptide. Elamipretide localises to the inner mitochondrial membrane and binds cardiolipin, a phospholipid that is important for mitochondrial membrane structure and function.

How Does It Work?

The FDA describes elamipretide as a mitochondrial cardiolipin binder that localises to the inner mitochondrial membrane and improves mitochondrial morphology and function. This mechanism is biologically relevant to disorders in which mitochondrial membrane integrity and cardiolipin are abnormal.

MECHANISM IS NOT AN INDICATION A mitochondrial mechanism does not by itself prove benefit for fatigue, athletic performance, recovery, metabolic health or healthy ageing.

What Does the Clinical Evidence Support?

In September 2025, the FDA granted accelerated approval to Forzinity (elamipretide) to improve muscle strength in adult and paediatric patients with Barth syndrome weighing at least 30 kg. The approval was based on improvement in knee extensor muscle strength, an intermediate endpoint, and continued approval may depend on confirmatory evidence.

Evidence is not uniformly positive across mitochondrial disorders. In the 2023 MMPOWER-3 randomised trial in primary mitochondrial myopathy, elamipretide did not improve six-minute walk distance or fatigue at 24 weeks compared with placebo.

Potential Areas of Clinical Interest

- Disease-specific mitochondrial and muscle function, where clinical evidence exists.
- Mitochondrial membrane and cardiolipin biology.
- Primary mitochondrial disease research, although efficacy differs by condition and study.
- Fatigue, exercise recovery and healthy-ageing applications remain unproven indications for this compounded pen.

Alchemy Compounding Pharmacy Presentation

Product detail	Alchemy SS-31 pen
Total contents	300 mg
Pen volume	3 mL
Concentration	100 mg/mL

Dose & Frequency

PATIENT-SPECIFIC PRESCRIBING The dose and frequency for the Alchemy compounded SS-31 pen must follow the individual prescription and the dispensing pharmacy label. Do not infer a regimen from the concentration or pen format, and do not substitute the disease-specific Forzinity regimen for this compounded presentation.

What is the Best Time of Day?

There is no robust evidence showing that a compounded SS-31 pen used outside its approved disease-specific context is more effective in the morning, before exercise or at bedtime. Timing should follow the prescription and be chosen consistently with clinical goals and tolerability.

How Long Should Treatment Continue?

There is no validated universal on/off cycling schedule for compounded SS-31 used for general mitochondrial or wellness goals. The long-term Forzinity programme in Barth syndrome is disease-specific and should not be translated into an automatic cycle for a compounded pen.

DURATION OF TREATMENT Use a defined clinical rationale and planned review point. Continuing or repeating treatment should depend on clinician reassessment, tolerability and measurable response rather than a fixed recurring cycle.

Possible Side Effects & Safety Considerations

Safety data are strongest for the FDA-approved elamipretide formulation and cannot be assumed to describe every compounded formulation. Clinically relevant reported concerns include:

- Injection-site reactions, including redness, pain, firmness, itching, bruising and hives.
- Hypersensitivity reactions, including serious allergic reactions requiring urgent treatment.
- Mild eosinophil elevations have been observed during elamipretide treatment.
- Renal impairment can increase elamipretide exposure and may materially affect clinical prescribing.
- Pregnancy and breastfeeding data in humans are limited.

SEEK MEDICAL ADVICE New, persistent or significant symptoms require medical review. Symptoms suggesting a serious allergic reaction require urgent medical attention.

Who Requires Particular Caution?

Particular caution is appropriate with significant renal impairment, a history of serious drug hypersensitivity, pregnancy or breastfeeding, active serious illness, and complex medication regimens. A clinician should assess whether the proposed use has a defensible clinical rationale and whether additional monitoring is required.

Clinical Review & Monitoring

- Confirm the clinical indication, treatment goals and baseline symptoms before treatment.
- Review renal function, allergy history and current medicines where clinically indicated.
- Assess tolerability and objective response at a planned review point.
- Reconsider treatment if meaningful benefit is not demonstrated or adverse effects develop.

Important

MEDICALLY SUPERVISED CARE Alchemy compounded SS-31 should not be represented as equivalent to FDA-approved Forzinity or as a proven treatment for fatigue, athletic performance, metabolic disease, recovery or healthy ageing. Patient counselling should distinguish established evidence from proposed or investigational uses.

Clinical references

FDA. Forzinity (elamipretide) Prescribing Information, September 2025; FDA Drug Trials Snapshot: Forzinity, May 2026; Karaa A et al. MMPOWER-3 randomized clinical trial of elamipretide in primary mitochondrial myopathy, Neurology (2023).