Elamipretide

Also called: SS-31; MTP-131; Bendavia; Forzinity; Elamipretida; Elamipretide hydrochloride

What it is

Elamipretide (SS-31, Bendavia; brand Forzinity) is a mitochondria-targeting, cardiolipin-binding tetrapeptide, D-Arg-dimethyl-Tyr-Lys-Phe-NH2, that steadies the inner mitochondrial membrane to improve energy production and reduce reactive oxygen species. The FDA granted it accelerated approval in September 2025 for Barth syndrome (muscle strength, patients >=30 kg), dosed 40 mg subcutaneously once daily; its primary-mitochondrial-myopathy phase 3 (MMPOWER-3, PMID 37268435) was not approved.

Approval status

FDA Approved. Approved: the FDA granted FORZINITY (elamipretide hydrochloride, Stealth BioTherapeutics) accelerated approval in September 2025 to improve muscle strength in adult and pediatric patients with Barth syndrome weighing at least 30 kg, based on improvement in knee-extensor strength, an intermediate endpoint (US label, DailyMed version 10, effective December 10, 2025). The separate primary-mitochondrial-myopathy programme, including the pivotal phase 3 MMPOWER-3, did not gain approval.

Dosing, as printed in the page's Recommended Dosing box

Manufacturer's recommended dosing (FDA label)

From the prescribing information. Other doses studied, if any, are in the full dosing data below.

Protocol and source	Dose	Frequency	Duration	Route
Barth syndrome, patients >=30 kg **[Approved label]** FORZINITY US prescribing information (DailyMed version 10, effective December 10, 2025)	40 mg	Once daily	Ongoing	Subcutaneous
Adults with severe renal impairment (eGFR <30, not on dialysis) **[Approved label]** FORZINITY US prescribing information (DailyMed version 10, effective December 10, 2025)	20 mg	Once daily	Ongoing	Subcutaneous

Educational information, not medical advice. Each dose above is tagged with its source: an approved label, a published human study, animal data, or amounts reported by users. None is a recommendation for you. An unapproved compound has no established safe or effective human dose, and products sold for "research use only" are not made or tested for people. Talk to a doctor before acting on anything on this site, including before you start, stop or change any medicine or dose.

Key human evidence

The first 3 of the 5 human studies carded on the page (6 study cards in all):

• **Phase 2 dose-escalation in mitochondrial myopathy** (Human, 2018). MMPOWER-1 assessed the safety, tolerability and efficacy of elamipretide, described as an aromatic-cationic tetrapeptide that readily enters cells and localises to the inner mitochondrial membrane where it associates with cardiolipin, in adults with primary mitochondrial myopathy. An early dose-escalation study, it set up the subcutaneous dosing and the outcome measures (notably the six-minute walk) carried into the later trials. **PMID 29500292**

• **Crossover trial of the subcutaneous form** (Human, 2020). MMPOWER-2 was a randomized, double-blind, placebo-controlled crossover trial of subcutaneous elamipretide in adults with primary mitochondrial myopathy, using the six-minute walk test, patient-reported fatigue, functional measures and safety to guide the design of the phase 3 trial. **PMID 32096613**

• **Pivotal phase 3 in mitochondrial myopathy (MMPOWER-3)** (Human, 2023). MMPOWER-3 was the pivotal phase 3 trial: participants with genetically confirmed primary mitochondrial myopathy were randomized one-to-one to 24 weeks of elamipretide 40 mg a day or placebo, given subcutaneously. The trial tested whether the drug improved physical function and quality of life in this broad group; its result did not support approval in mitochondrial myopathy, and the drug was not approved for that use. **PMID 37268435**

Interactions

A PubMed search for interaction studies of this compound with any drug (November 5, 2026, 3 records) found none in people. That is not evidence that it is safe to combine with anything.

Side effects and cautions

Reported side effects	Contraindications and cautions
• Given by daily subcutaneous injection; injection-site reactions are a typical class effect of such drugs • The dose is reduced in adults with severe renal impairment (eGFR below 30), per the label • The product contains the preservative benzyl alcohol; the label advises against use where this is a concern (follow the product label) • As an accelerated approval, continued approval may depend on trials confirming clinical benefit • Full, current safety information is in the FORZINITY prescribing information, which governs its use	• Approved only to improve muscle strength in Barth syndrome in patients weighing at least 30 kg; other uses are not approved • The dose must be reduced in severe renal impairment; no regimen is established for eGFR <30 on dialysis (label) • A prescription medicine to be used under specialist supervision, not a self-directed supplement • Its studied uses in mitochondrial myopathy, heart failure and eye disease are investigational and not approved

Five questions to ask

1. Is Elamipretide right for me, and is the labelled dose on this sheet right for my weight, age, kidney and liver function?
2. Here are the medicines and supplements I take. Do any of them interact with Elamipretide? This sheet records none published, which does not mean none exist.
3. Which side effects should make me stop and call you, for example given by daily subcutaneous injection?
4. Do any of the cautions on this sheet apply to me, such as: Approved only to improve muscle strength in Barth syndrome in patients weighing at least 30 kg?

5. What should we check before I start and while I am on it (blood tests, blood pressure, weight), and how often?

Grey Peptides is a vendor-neutral encyclopedia: it sells nothing and names no seller. This sheet is educational, not medical advice, and is not a prescription.