

PATIENT GUIDE

SS-31 *elamipretide*

What elamipretide does inside your mitochondria, the one condition it is approved to treat, and what human trials have and have not shown.

COMPOUND	CLASS	ROUTE	APPROVED FOR	SOURCES
Elamipretide	Cardiolipin binder	Under the skin	Barth syndrome	30 · PMID linked

§ 01

Why we are talking about SS-31

SS-31, known in medicine as elamipretide, stands apart from most peptides discussed in longevity medicine because it has completed formal drug development. It was designed in a laboratory to reach the innermost membrane of the mitochondria, the structures that make most of your cellular energy, and in September 2025 it became an FDA approved medicine for a rare inherited mitochondrial condition called Barth syndrome.^{1 29} That approval, and the large number of human trials behind it, are why patients ask us about it.

This guide explains what elamipretide does, the one use it is approved for, and what human trials in other conditions have and have not shown, the encouraging results and the disappointing ones alike. It also covers how the medicine is given, its known side effects, and its regulatory status. Every source is listed at the end with a link so you can read it yourself.

Sept 2025	FDA approval for Barth syndrome. Elamipretide, sold as FORZINITY, became the first treatment approved specifically for Barth syndrome, under the FDA accelerated approval pathway. ^{1 29}
40 mg	The approved daily dose. One injection under the skin each day, for patients with Barth syndrome who weigh at least 30 kg. ²⁸
218	Adults in the largest trial. In primary mitochondrial myopathy, 24 weeks of daily elamipretide did not improve walking distance or fatigue compared with placebo. It was well tolerated. ²
39	Healthy older adults studied. In people aged 60 to 85, a single infusion briefly raised the energy capacity of a hand muscle, without a change in how quickly the muscle tired. ³

What SS-31 is

Elamipretide is a very small peptide, a chain of just four amino acids. It belongs to the Szeto-Schiller peptides, named after the two scientists who designed them to pass through cell membranes and gather on the inner membrane of the mitochondria, which is where the name SS-31 comes from.^{4 5}

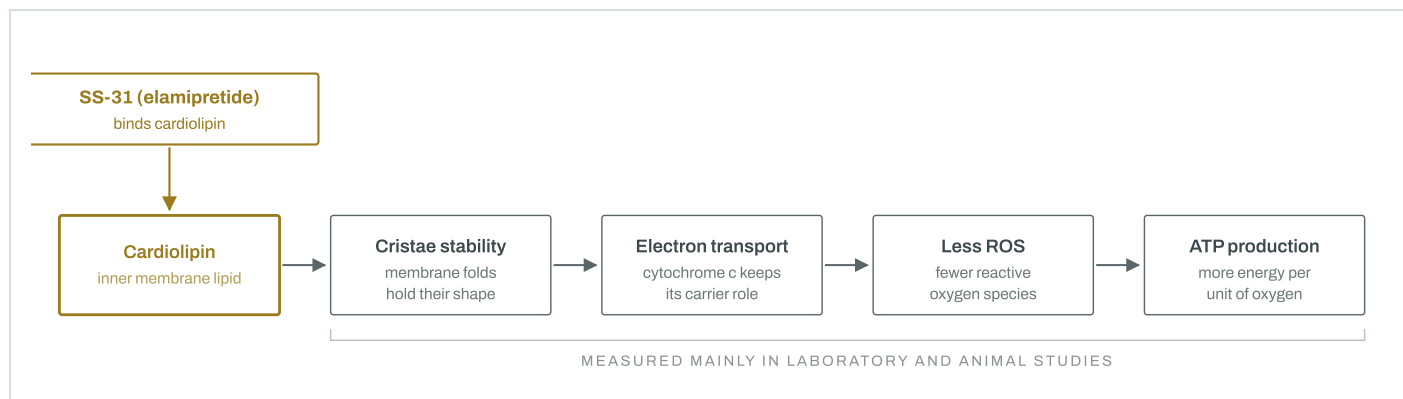
One of its four building blocks, arginine, is in its mirror image (D) form, and another is a modified tyrosine.²⁸ Its positively charged and ring shaped (aromatic) building blocks let it attach to cardiolipin, both by electrical attraction and by tucking into the membrane.^{5 6} The FDA describes elamipretide as a mitochondrial cardiolipin binder.²⁸

ELAMIPRETIDE AT A GLANCE	
Name	Elamipretide
Also called	SS-31, MTP-131, Bendavia; brand name FORZINITY ^{7 28}
Sequence	Four amino acids: D-Arg-2,6-dimethyl-Tyr-Lys-Phe-NH ₂ ²⁸
Origin	Synthetic, designed in the laboratory as one of the Szeto-Schiller peptides ⁴
Class	Mitochondrial cardiolipin binder ²⁸
How it is given	Injection under the skin once daily (approved route). Intravenous infusion and eye drops have been used only in research ^{28 8 9}

How SS-31 works

Each mitochondrion has two membranes. The inner one is folded into deep ridges called cristae, and this is where the chain of enzymes that makes ATP, the energy currency of the cell, is housed. Holding those folds in shape is a fat molecule (a phospholipid) called cardiolipin, which is found only on this inner membrane. Cardiolipin also keeps the energy enzymes grouped together so electrons can pass efficiently from one to the next.⁵

When cells are under stress, cardiolipin can bind a small protein called cytochrome c in a way that changes its job. Instead of carrying electrons, cytochrome c starts to oxidize the membrane around it, which damages cardiolipin and the cristae it supports.^{5 10} Elamipretide attaches selectively to cardiolipin.¹⁰ In laboratory experiments this prevented cytochrome c from switching into that damaging mode while preserving its normal electron carrying role, and in fresh mitochondria it increased the efficiency of ATP production.⁶



Elamipretide acts on the membrane where cellular energy is made. By binding cardiolipin, it helps preserve the folded cristae and the electron carrying role of cytochrome c, and in isolated mitochondria it made ATP production more efficient. ^{5 6} In old mice it lowered the release of reactive oxygen species from muscle mitochondria. ¹¹

These steps have been worked out mainly in isolated mitochondria, cells and animals. ^{5 10} Human evidence for the same chain is more limited but real. In heart tissue removed from people with heart failure and studied in the laboratory, elamipretide improved the activity of the energy enzymes. ¹² In a randomized trial in healthy older adults, a single infusion raised the maximum ATP production of a hand muscle immediately afterward, and the effect was gone a week later. ³

Barth syndrome is an inherited condition in which a faulty gene causes abnormal cardiolipin on the inner mitochondrial membrane. ¹³ That makes it the clearest possible match for a medicine that works on cardiolipin, and it is the condition in which the FDA approved it. ²⁸

WHY THIS IS USEFUL TO KNOW

In Barth syndrome the cardiolipin problem is the disease itself. ¹³ In most other conditions, and in ordinary aging, mitochondrial changes are one factor among many. That is a reasonable way to understand why the mechanism is well supported in the laboratory, while larger human trials outside Barth syndrome have mostly not reached their main goals. ^{2 14 15}

§ 04

What the research shows

Elamipretide has been tested in many human trials across several conditions, which gives a clearer picture than exists for most peptides, including results the investigators did not hope for.

What is well established

Barth syndrome. The approval rests on the TAZPOWER trial. Twelve patients were randomized to 12 weeks of elamipretide 40 mg daily and 12 weeks of placebo in turn, and in that randomized phase neither main goal, walking distance and a symptom score, was met. ¹³ Ten patients continued on elamipretide in an open label extension. By week 36 of the extension their six minute walk distance had improved by 95.9 meters and their symptom scores had improved. ¹³ Eight patients reached week 168, with a cumulative walking improvement of 96.1 meters and favorable trends in heart pumping volumes. ¹⁶ Compared with 19 untreated patients followed in a natural history study,

treated patients walked 91.0 meters farther at week 76.¹⁷ The FDA based its accelerated approval on knee muscle strength: the median gain from baseline was 63 newtons at week 168 in the open label extension, while no increase was seen during the 12 week randomized phase.²⁸

Tolerability and mechanism. Across trials lasting from days to more than three years, elamipretide has been well tolerated, and the most common side effect by far is a reaction at the injection site.^{28 2 15} Its binding to cardiolipin and its effects on mitochondrial energy production are well described in laboratory and animal work.^{5 6}

What is still being defined

Mitochondrial muscle disease. A first trial of intravenous elamipretide for five days showed a trend toward longer walking distance at the highest dose (64.5 meters compared with 20.4 meters on placebo), which narrowly missed statistical significance.⁸ A four week trial of daily injections found a 19.8 meter difference that was not statistically significant, with nominal improvements in patient reported fatigue.¹⁸ The definitive phase 3 trial, MMPOWER-3, enrolled 218 adults for 24 weeks and did not meet its goals: walking distance and fatigue did not differ from placebo.² A later analysis suggested that a subgroup with one type of genetic cause may respond, and a new phase 3 trial has been designed to test that idea.¹⁹

Heart and kidney. Given as a one hour infusion during emergency treatment of a heart attack, elamipretide did not reduce the size of the heart muscle injury.²⁰ In heart failure, a single four hour infusion at the highest dose reduced the volume of the left ventricle by the end of the infusion,²¹ but 28 days of daily injections in 71 patients did not improve heart size or pumping function compared with placebo.¹⁴ A small pilot study during stenting of a narrowed kidney artery found less oxygen shortage in the kidney afterward and better blood flow at three months.²²

Eyes. In two small open label studies in adults aged 55 and over with macular degeneration, vision, particularly in dim light, improved over 24 weeks, although there was no comparison group.^{23 24} The larger randomized ReCLAIM-2 trial in 176 patients did not meet its main goals for vision or the growth of atrophy, but in an exploratory analysis it showed slower loss of the light sensing layer of the retina, a measure now chosen as the main goal of the phase 3 program.¹⁵ Eye drops tested in a rare inherited optic nerve condition did not meet their main goal.⁹

Aging and healthy adults. Here the human data are thin. The single randomized trial in healthy older adults showed a brief rise in muscle energy capacity after one infusion, with no change in muscle fatigue and no effect a week later.³ The more striking aging results come from mice. In old mice, a single dose restored muscle energy production to young levels within an hour,¹¹ eight weeks of treatment improved treadmill endurance²⁵ and reversed the age related decline in the heart's ability to relax between beats,²⁶ and a 2025 study found less frailty but no change in measures of biological age.²⁷ These are animal results. No trial has yet tested whether elamipretide improves health, function or lifespan in healthy people over months or years.

KEY HUMAN STUDIES Results are shown as the investigators reported them for the main goal of each study.			
STUDY	N	DESIGN	FINDING
TAZPOWER, Barth syndrome (2021, 2024) ^{13 16}	12	Randomized crossover, 12 weeks each arm, then open label to 168 weeks	NOT MET in randomized phase; IMPROVED walking by 96.1 m in the 8 who reached week 168
MMPOWER, mitochondrial myopathy (2018) ⁸	36	Randomized, intravenous, 5 days	TREND 64.5 vs 20.4 m at highest dose

STUDY	N	DESIGN	FINDING
MMPOWER-2 (2020) ¹⁸	30	Randomized crossover, 4 weeks of injections	NOT MET on walking; fatigue scores improved
MMPOWER-3 (2023) ²	218	Phase 3 randomized, 24 weeks of injections	NOT MET no difference in walking or fatigue
EMBRACE STEMI , heart attack (2016) ²⁶	300 ³⁹	Randomized, 1 hour infusion during treatment	NOT MET no reduction in heart muscle injury
Heart failure infusion (2017) ²¹	36	Randomized, single 4 hour infusion	EARLY SIGNAL smaller heart volumes at end of infusion, highest dose
PROGRESS-HF , heart failure (2020) ¹⁴	71	Randomized, 28 days of injections	NOT MET no change in heart size or function
Kidney artery stenting (2017) ²²	14	Placebo controlled pilot, infusion during stenting	EARLY SIGNAL less kidney oxygen shortage, better blood flow
ReCLAIM , dry macular degeneration (2022) ^{23 24}	19 and 21	Open label, 24 weeks of injections	EARLY SIGNAL dim light vision improved, no control group
ReCLAIM-2 (2025) ¹⁵	176	Randomized, 48 weeks of injections	NOT MET on main goals; slower retinal layer loss
Eye drops , inherited optic neuropathy (2024) ⁹	12	Randomized, vehicle controlled, 52 weeks	NOT MET on visual acuity; well tolerated
Healthy older adults , muscle (2021) ³	39	Randomized, single 2 hour infusion	BRIEF EFFECT muscle ATP capacity rose, no change in fatigue

HOW WE WOULD SUMMARIZE IT

Elamipretide is a carefully studied medicine with a clear mechanism and a reassuring safety record. It has earned FDA approval in the one condition where cardiolipin is the root problem. Outside Barth syndrome, larger trials have mostly not met their main goals, and in healthy adults the evidence is limited to a single dose study and to animal research. For a patient interested in mitochondrial health, that is an honest starting point for a conversation, and we will give you our view based on your own situation.

§ 05

How SS-31 is given

Elamipretide has been given three ways in human research: under the skin, by intravenous infusion, and as eye drops. Only the first is approved. ²⁸

Injection under the skin (the approved route)

For Barth syndrome, the approved dose is 40 mg injected under the skin once a day, at about the same time each day, into the abdomen at least two inches from the navel or into the outer thigh, rotating the site daily. If a dose is missed, it is skipped rather than doubled. For adults with severely reduced kidney function who are not on dialysis, the dose

is halved to 20 mg.²⁸ FORZINITY comes in a vial that holds several daily doses and contains the preservative benzyl alcohol; an opened vial is discarded after 8 days.²⁸

After an injection, blood levels peak within 30 to 60 minutes. About 92 percent of the dose reaches the circulation, it is broken down into inactive fragments, and essentially all of it leaves the body in urine within 48 hours.²⁸

The same 40 mg daily dose was used in the trials in mitochondrial myopathy and macular degeneration,^{2 15} and a heart failure trial compared 4 mg and 40 mg daily.¹⁴ For any use other than Barth syndrome, no regulator has set a dose, and the dose is set by your physician.

Intravenous infusion (research only)

Many of the earlier trials gave elamipretide through a vein, with doses calculated by body weight and infusions lasting one to four hours.^{20 21 8 3} Levels peaked at the end of the infusion and were undetectable by 24 hours.²¹ FORZINITY is not approved for intravenous use.²⁸

Eye drops (research only)

A 1 percent eye drop was tested for up to three years in a small trial in an inherited optic nerve condition. It was well tolerated but did not improve visual acuity compared with the control drops.⁹ No eye drop product is approved.

By mouth or nasal spray

We are not aware of any published human studies of elamipretide taken by mouth or as a nasal spray. For that reason we cannot describe how well either would be absorbed or what dose would be appropriate.

COMPARING THE OPTIONS				
	UNDER THE SKIN	INTRAVENOUS	EYE DROPS	BY MOUTH OR NASAL
Status	FDA APPROVED for Barth syndrome ²⁸	Research only ²⁸	Research only ⁹	Not studied
Dose in studies	40 mg once daily ²⁸	Weight based, 1 to 4 hours ^{20 21}	1 percent solution ⁹	None published
Common experience	Redness, itching, tenderness or firmness at the site ²⁸	No serious adverse events in the heart failure study ²¹	Mostly mild effects that settled on their own ⁹	Unknown

§ 06

What to expect

Elamipretide is a daily injection under the skin. After training, adults can give it themselves at home if their physician agrees.²⁸ Reactions at the injection site are expected. In the Barth syndrome trial, all 12 patients had some redness at the site, and itching, firmness and tenderness were common. The label advises that these reactions can be eased with antihistamines or steroid creams.²⁸

Benefits, where they have been seen, have taken time. In Barth syndrome, no gain in muscle strength was measured during the first 12 weeks of the randomized phase; the gains appeared during the months of continued treatment that followed.^{28 13} In healthy older adults, the only measured effect was a brief rise in muscle energy capacity after a

single infusion, which had faded within a week and did not change how quickly the muscle tired. ³ We therefore cannot promise a noticeable change in energy on any particular timeline.

Your blood count may show a rise in a type of white cell called eosinophils. This was common with 30 days or more of treatment, tended to peak around 90 days, returned to baseline over 6 to 12 months or after stopping, and was not linked to symptoms. ²⁸

DURING YOUR FIRST WEEKS

- Rotate between the abdomen and outer thighs, and avoid skin that is tender, bruised, red, hard or scarred. ²⁸
- Tell us promptly about a spreading rash, hives away from the injection site, cough, or any sign of an allergic reaction. Seek emergency care for swelling of the face or throat, or difficulty breathing. ²⁸

§ 07

Safety

The safety picture from human trials is reassuring. In the largest trial, 24 weeks of daily injections in 218 adults were well tolerated, with most side effects mild to moderate. ² In the 48 week macular degeneration trial, side effects of any kind were reported by 86 percent of patients on elamipretide and 71 percent on placebo, most often injection site reactions. ¹⁵ The table shows the reactions in the placebo controlled phase of the Barth syndrome trial.

INJECTION SITE REACTIONS IN THE BARTH SYNDROME TRIAL ¹² patients, each treated with elamipretide and with placebo ²⁸		
REACTION	ELAMIPRETIDE	PLACEBO
Any injection site reaction	12 (100%)	8 (67%)
Redness	12 (100%)	3 (25%)
Pain	9 (75%)	5 (42%)
Firmness	8 (67%)	2 (17%)
Itching	8 (67%)	2 (17%)
Bruising	3 (25%)	0
Hives at the site	3 (25%)	0

The label carries two warnings. Allergic reactions, including serious ones that needed emergency treatment, have been reported, with rashes or cough, beginning anywhere from minutes to months after starting. The preservative benzyl alcohol can be dangerous for newborns, so the product is not used in neonates. Heart rhythm testing showed no clinically significant QTc prolongation, and elamipretide did not interfere with aspirin, clopidogrel or heparin. ²⁸

TELL YOUR PHYSICIAN BEFORE STARTING IF ANY OF THESE APPLY

- You have ever had an allergic reaction to elamipretide, to benzyl alcohol, or to another injected medicine.²⁸
- You have kidney disease, since reduced kidney function raises blood levels and may call for a lower dose.²⁸
- You are pregnant, trying to conceive, or breastfeeding. There are no human data in pregnancy or breastfeeding.²⁸
- You have heart disease, a mitochondrial or other genetic condition, or an eye condition such as macular degeneration, so any treatment can be coordinated with your specialist.
- You take any prescription medication, over the counter product or supplement. Please bring the full list.

The longest human follow up is in Barth syndrome, where 8 patients were treated for 168 weeks and 3 for 192 weeks. The Barth syndrome studies did not include anyone aged 65 or older, and long term cancer studies in animals have not been carried out.²⁸ There are no long term data in healthy adults using elamipretide for general wellness.

§ 08

Is this right for you

Elamipretide is a good fit for a small number of patients and not the right starting point for many others. The purpose of your consultation is to work out, together, which is true for you.

Before we begin

- | | |
|--------------------------|--|
| ☐ | A review of your medical history, current medications and supplements |
| ☐ | Blood pressure, heart rate and weight, and any other measurements your physician feels are warranted |
| ☐ | Baseline bloodwork, so that anything we see later can be compared against a starting point |
| ☐ | A clear note of what you are hoping to feel, written down, so we can tell together whether it worked |

If low energy, reduced exercise tolerance or muscle weakness is what brings you in, those symptoms have many causes, including thyroid problems, anemia, sleep disorders and medication effects. Finding and treating one of those would be a better outcome for you than any peptide, so we look for them first.

Reviewing your progress

We will reassess against your documented starting point after a defined period rather than leaving treatment open ended. If you are doing well, we will plan how to continue. If you are not, we will say so and look at other options. You are welcome to stop at any time.

QUESTIONS WORTH ASKING US

What would you expect me to notice, and by when? How will we measure whether this is working? Is this the FDA approved product or a compounded preparation? What would make you recommend stopping? We are glad to answer all of these, and a good clinic should welcome them.

§ 09

Regulatory status, stated plainly

Elamipretide is an FDA approved drug. On 19 September 2025 the FDA granted accelerated approval to FORZINITY to improve muscle strength in adult and pediatric patients with Barth syndrome weighing at least 30 kg. ^{29 28}

Accelerated approval means the decision was based on an intermediate measure, in this case knee muscle strength, and the FDA has required a further randomized, placebo controlled trial to confirm that this translates into benefit for patients. ^{29 28}

Any other use, including for longevity, energy, or mitochondrial support in healthy adults, is off label. Prescribing an approved medicine off label is lawful and common in American medicine, and it is a decision your physician makes with you. It does mean that no regulator has reviewed elamipretide for that purpose, and you should know that before you consent.

If a compounded preparation of elamipretide is used, it is prepared by a licensed compounding pharmacy on a physician's prescription. A compounded preparation is not the FDA approved product. It has not been reviewed by the FDA for safety, effectiveness or quality, and it may differ from FORZINITY in strength, ingredients and preservative.

If you compete in a tested sport, check the current World Anti-Doping Agency Prohibited List and speak with your sport's drug testing authority before starting any new medicine, including this one.

If you would like details about the preparation used in your treatment, please ask.

References

Every source below is indexed in PubMed or published by the FDA or ClinicalTrials.gov

- 1 **Shirley M.** Elamipretide: first approval.
Drugs. 2026;86(3):377-383. [PMID 41335372](#)
- 2 **Karaa A, et al.** Efficacy and safety of elamipretide in individuals with primary mitochondrial myopathy: the MMPOWER-3 randomized clinical trial.
Neurology. 2023;101(3):e238-e252. [PMID 37268435](#)
- 3 **Roshanravan B, et al.** In vivo mitochondrial ATP production is improved in older adult skeletal muscle after a single dose of elamipretide in a randomized trial.
PLoS One. 2021;16(7):e0253849. [PMID 34264994](#)
- 4 **Szeto HH, Schiller PW.** Novel therapies targeting inner mitochondrial membrane: from discovery to clinical development.
Pharm Res. 2011;28(11):2669-2679. [PMID 21638136](#)
- 5 **Szeto HH.** First-in-class cardiolipin-protective compound as a therapeutic agent to restore mitochondrial bioenergetics.
Br J Pharmacol. 2014;171(8):2029-2050. [PMID 24117165](#)

- 6 **Birk AV, et al.** Targeting mitochondrial cardiolipin and the cytochrome c/cardiolipin complex to promote electron transport and optimize mitochondrial ATP synthesis.
Br J Pharmacol. 2014;171(8):2017-2028. [PMID 24134698](#) · laboratory study

- 7 **Tung C, et al.** Elamipretide: a review of its structure, mechanism of action, and therapeutic potential.
Int J Mol Sci. 2025;26(3):944. [PMID 39940712](#)

- 8 **Karaa A, et al.** Randomized dose-escalation trial of elamipretide in adults with primary mitochondrial myopathy.
Neurology. 2018;90(14):e1212-e1221. [PMID 29500292](#)

- 9 **Karanjia R, Sadun AA.** Elamipretide topical ophthalmic solution for the treatment of subjects with Leber hereditary optic neuropathy: a randomized trial.
Ophthalmology. 2024;131(4):422-433. [PMID 37923251](#)

- 10 **Birk AV, et al.** The mitochondrial-targeted compound SS-31 re-energizes ischemic mitochondria by interacting with cardiolipin.
J Am Soc Nephrol. 2013;24(8):1250-1261. [PMID 23813215](#) · laboratory and rat study

- 11 **Siegel MP, et al.** Mitochondrial-targeted peptide rapidly improves mitochondrial energetics and skeletal muscle performance in aged mice.
Aging Cell. 2013;12(5):763-771. [PMID 23692570](#) · animal study

- 12 **Chatfield KC, et al.** Elamipretide improves mitochondrial function in the failing human heart.
JACC Basic Transl Sci. 2019;4(2):147-157. [PMID 31061916](#) · human heart tissue studied in the laboratory

- 13 **Reid Thompson W, et al.** A phase 2/3 randomized clinical trial followed by an open-label extension to evaluate the effectiveness of elamipretide in Barth syndrome, a genetic disorder of mitochondrial cardiolipin metabolism.
Genet Med. 2021;23(3):471-478. [PMID 33077895](#)

- 14 **Butler J, et al.** Effects of elamipretide on left ventricular function in patients with heart failure with reduced ejection fraction: the PROGRESS-HF phase 2 trial.
J Card Fail. 2020;26(5):429-437. [PMID 32068002](#)

- 15 **Ehlers JP, et al.** ReCLAIM-2: a randomized phase II clinical trial evaluating elamipretide in age-related macular degeneration, geographic atrophy growth, visual function, and ellipsoid zone preservation.
Ophthalmol Sci. 2025;5(1):100628. [PMID 39605874](#)

- 16 **Thompson WR, et al.** Long-term efficacy and safety of elamipretide in patients with Barth syndrome: 168-week open-label extension results of TAZPOWER.
Genet Med. 2024;26(7):101138. [PMID 38602181](#)

- 17 **Hornby B, et al.** Natural history comparison study to assess the efficacy of elamipretide in patients with Barth syndrome.
Orphanet J Rare Dis. 2022;17(1):336. [PMID 36056411](#)

- 18 **Karaa A, et al.** A randomized crossover trial of elamipretide in adults with primary mitochondrial myopathy.
J Cachexia Sarcopenia Muscle. 2020;11(4):909-918. [PMID 32096613](#)

- 19 **Karaa A, et al.** Genotype-specific effects of elamipretide in patients with primary mitochondrial myopathy: a post hoc analysis of the MMPOWER-3 trial.
Orphanet J Rare Dis. 2024;19(1):431. [PMID 39574155](#)

- 20 **Gibson CM, et al.** EMBRACE STEMI study: a Phase 2a trial to evaluate the safety, tolerability, and efficacy of intravenous MTP-131 on reperfusion injury in patients undergoing primary percutaneous coronary intervention.
Eur Heart J. 2016;37(16):1296-1303. [PMID 26586786](#)

- 21 **Daubert MA, et al.** Novel mitochondria-targeting peptide in heart failure treatment: a randomized, placebo-controlled trial of elamipretide.
Circ Heart Fail. 2017;10(12):e004389. [PMID 29217757](#)

- 22 **Saad A, et al.** Phase 2a clinical trial of mitochondrial protection (elamipretide) during stent revascularization in patients with atherosclerotic renal artery stenosis.
Circ Cardiovasc Interv. 2017;10(9):e005487. [PMID 28916603](#)

- 23 **Mettu PS, Allingham MJ, Cousins SW.** Phase 1 clinical trial of elamipretide in dry age-related macular degeneration and noncentral geographic atrophy: ReCLAIM NCGA study.

-
- 24 **Allingham MJ, Mettu PS, Cousins SW.** Phase 1 clinical trial of elamipretide in intermediate age-related macular degeneration and high-risk drusen: ReCLAIM high-risk drusen study.
Ophthalmol Sci. 2022;2(1):100095. PMID 36246187
-
- 25 **Campbell MD, et al.** Improving mitochondrial function with SS-31 reverses age-related redox stress and improves exercise tolerance in aged mice.
Free Radic Biol Med. 2019;134:268-281. PMID 30597195 · animal study
-
- 26 **Chiao YA, et al.** Late-life restoration of mitochondrial function reverses cardiac dysfunction in old mice.
Elife. 2020;9:e55513. PMID 32648542 · animal study
-
- 27 **Mitchell W, et al.** The mitochondria-targeted peptide therapeutic elamipretide improves cardiac and skeletal muscle function during aging without detectable changes in tissue epigenetic or transcriptomic age.
Aging Cell. 2025;24(6):e70026. PMID 40080911 · animal study
-
- 28 **U.S. Food and Drug Administration.** FORZINITY (elamipretide) injection, for subcutaneous use. Prescribing information, NDA 215244, revised September 2025.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215244s000lbl.pdf · accessed 26 September 2026.
-
- 29 **U.S. Food and Drug Administration.** FDA grants accelerated approval for first treatment of Barth syndrome. Press announcement, 19 September 2025.
<https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-first-treatment-barth-syndrome> · accessed 26 September 2026.
-
- 30 **ClinicalTrials.gov.** Evaluation of Myocardial Effects of MTP-131 for Reducing Reperfusion Injury in Patients With Acute Coronary Events (EMBRACE STEMI), NCT01572909.
<https://clinicaltrials.gov/study/NCT01572909> · enrollment 300 (actual) · accessed 26 September 2026.
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IMPORTANT NOTICE

This document is patient education prepared by Regen Therapy MD. It is not medical advice, not a prescription, and not a promise of any clinical outcome. **Elamipretide (FORZINITY) received FDA accelerated approval in September 2025 only to improve muscle strength in adult and pediatric patients with Barth syndrome weighing at least 30 kg; any other use, including for longevity or mitochondrial support, is off label, and a compounded preparation is not the FDA approved product.** Individual results vary, and no outcome can be predicted from the studies cited here.

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REVIEWING PHYSICIAN

RTMD-WP-022 · Version 1.0 · 26 September 2026 · Next scheduled literature review: March 2027 · Prepared with sources indexed in PubMed and FDA public records.