SS 31 was administered by IV drip over 2 hours.

SS-31 (elamipretide) has indeed been given as a 2-hour IV infusion in human studies, typically at fixed mg/kg/hour rates.[1] [2]

Typical IV infusion parameters

- In a randomized dose-escalation trial in adults with primary mitochondrial myopathy, elamipretide was infused intravenously for 2 hours at rates of 0.01, 0.1, or 0.25 mg/kg/hour, with good short-term tolerability and no major safety signals.[2]
- Another clinical study in heart failure patients reported IV elamipretide infusions at 0.25 mg/kg/hour over 4 hours, and a separate phase I safety study in healthy volunteers used 0.05 mg/kg/hour for 2 hours without drug-related adverse events.[1]

Safety and pharmacokinetics

- Across phase I trials, IV SS-31 was described as well tolerated over a wide dose range (0.01–0.25 mg/kg/hour) for infusion durations up to 4 hours, achieving pharmacologically active plasma levels at even the lowest tested dose.[3] [1]
- Reported adverse effects with short IV infusions have been minimal, and serious toxicity has not emerged in these early-stage studies, though larger and longer trials are still needed for definitive safety conclusions.[2] [1]

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what dose was used in the trials that resulted in ss 31 being approved as a drug

The pivotal trials that led to approval used a daily subcutaneous dose of 40 mg elamipretide (SS-31), given once per day.[22] [23] [24]

Approved dose

- The FDA prescribing information for Forzinity (elamipretide) specifies a recommended dose of 40 mg subcutaneously once daily in patients weighing at least 30 kg.[23] [22]
- Each single-patient-use vial contains 280 mg in 3.5 mL (80 mg/mL), from which a 0.5 mL dose delivers the 40 mg daily amount.[25]

Dose used in key trials

- In the phase 2/3 Barth syndrome trial and subsequent studies forming the clinical basis for approval, participants were randomized to receive 40 mg elamipretide subcutaneously once daily versus placebo, generally over 12–24 weeks before open-label extension. [26] [24] [27]
- Long-term extension data also continued the same 40 mg once-daily subcutaneous regimen to assess durability of effect and safety, reinforcing this as the standard therapeutic dose. [28] [22]

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