

## SS – 31 (Elamipretide)

### What is SS-31?

SS-31, also known as Elamipretide, is a synthetic tetrapeptide developed to target and protect mitochondria—the energy-producing centers of cells. By binding to cardiolipin, a phospholipid located on the inner mitochondrial membrane, SS-31 reduces oxidative stress and prevents mitochondrial dysfunction. This makes it a potential therapeutic option for diseases linked to mitochondrial damage, such as cardiovascular conditions, neurodegenerative disorders, and age-related muscle decline.

Research has demonstrated SS-31's potential in improving outcomes for patients with mitochondrial diseases, age-related muscle loss, and even heart conditions caused by mitochondrial dysfunction. By reducing oxidative stress, SS-31 helps cells to recover and operate more effectively, potentially slowing the aging process and alleviating mitochondrial diseases.

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### Potential Benefits

#### 1. Cardiovascular Health

- **Improvement in Heart Function:** Enhances mitochondrial function in heart muscle cells, which may help in heart failure or ischemia-reperfusion injury (damage caused by restored blood flow after a period of ischemia or lack of oxygen).
- **Reduction in Myocardial Ischemia:** May reduce tissue damage in conditions like heart attacks.
- **Blood Pressure Regulation:** Helps in restoring vascular health by improving endothelial function.

#### 2. Neuroprotection

- **Prevention of Neurodegeneration:** Shown to protect neurons from mitochondrial dysfunction, potentially benefiting conditions like Alzheimer's, Parkinson's, and Huntington's diseases.
- **Cognitive Improvement:** May improve memory and learning capabilities by preserving mitochondrial health in brain cells.

#### 3. Muscle Health

- **Prevention of Age-Related Muscle Loss (Sarcopenia):** Protects mitochondria in skeletal muscles, improving muscle strength and endurance.
- **Enhancement of Exercise Performance:** Helps in reducing fatigue and improving recovery by increasing mitochondrial efficiency in muscle cells.

#### 4. Kidney Health

- Protection Against Acute Kidney Injury (AKI): Reduces mitochondrial dysfunction and oxidative damage in kidney cells.
- Chronic Kidney Disease (CKD): May slow the progression of CKD by improving mitochondrial function in renal tissues.

## 5. Vision Improvement

- Protection in Retinal Disorders: Demonstrates potential in protecting against age-related macular degeneration (AMD) and other retinal degenerative diseases by reducing oxidative stress in retinal cells.

## 6. Anti-Aging Effects

- Reduction in Cellular Senescence: By reducing oxidative stress and mitochondrial dysfunction, it slows the aging process at the cellular level.
- Improved Energy Levels: Enhances overall cellular energy production, reducing fatigue associated with aging.

## 7. Mitochondrial Diseases

- Therapeutic for Rare Disorders: Shows promise for treating rare mitochondrial disorders, such as primary mitochondrial myopathies.

## 8. Metabolic Health

- Improved Insulin Sensitivity: By reducing oxidative stress and improving mitochondrial function, it may help in managing insulin resistance and metabolic syndrome.

## 9. Skin Health

- Anti-Wrinkle Effects: May protect skin cells from oxidative damage, reducing signs of aging like wrinkles and loss of elasticity.

## 10. Cancer Therapy (Investigational)

- Adjunct to Treatments: Could potentially protect healthy cells during chemotherapy or radiation therapy by preserving mitochondrial integrity.

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## Potential Side Effects and Precautions

While SS-31 (Elamipretide) has shown promising therapeutic benefits, its side effects and safety profile are still under investigation. Here's what is currently known based on clinical trials and preclinical studies:

### 1. Injection Site Reactions

- Redness, swelling, or discomfort at the site of injection.
- Common with subcutaneous administration of SS-31.

### 2. Mild Gastrointestinal Symptoms

- Nausea, vomiting, or diarrhea.
- These effects are typically mild and transient.

### 3. Headache

- Occasional reports of headaches, likely related to systemic effects.

### 4. Fatigue

- Some participants in trials reported feeling more tired, especially at higher doses.

### 5. Dizziness

- Possibly due to blood pressure fluctuations or mitochondrial changes affecting systemic energy metabolism.

### 6. Hypotension

- Changes in vascular function might lead to episodes of low blood pressure in some cases.

### 7. Allergic Reactions (Rare)

- As with any peptide-based therapy, there's a risk of hypersensitivity or allergic reactions.

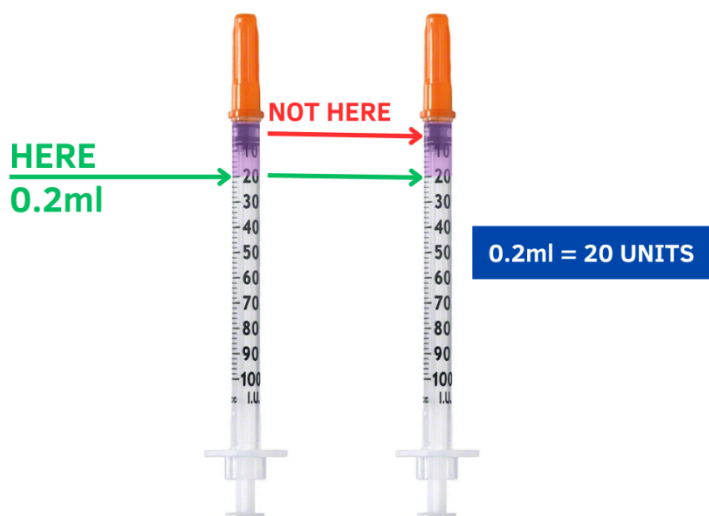
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## Dosage Guidelines

**Acute Conditions:** 2 mg (0.2ml or 20 units) SQ daily for 2-4 **days**

**Chronic Conditions:** 2 mg (0.2ml or 20 units) SQ daily for 2-4 **weeks**

### 0.2ml - 20 units (Not 2 units)



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## Cost

SS-31 is currently only available as a research peptide. Please see document titled *“Research Peptide Information”* in the Education Folder under Records in the patient portal.

**SS-31: 10mg Vial (10mg/ml):** \$118.50 (includes shipping and bacteriostatic water). **One vial = 5 days.**

**SS-31 25mg Vial (10mg/ml):** \$228.50 (includes shipping and bacteriostatic water). **One vial = 12 days.**

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## Reconstitution Instructions

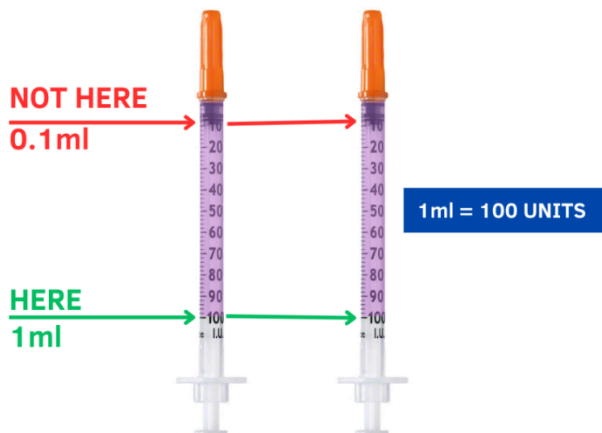
### IMPORTANT:

- Follow the instructions below regarding the amount of bacteriostatic water to use when reconstituting the peptide. **DO NOT** follow the instructions that come with the peptide.
- **Do NOT** throw away the vial of bacteriostatic water!!! It is a multiuse vial and can be used for your next order!

### 10mg Vial

- Inject **1ml of bacteriostatic water** into the vial (1ml = 100 units).

**1 ml - 100 units (Not 10 UNITS)**



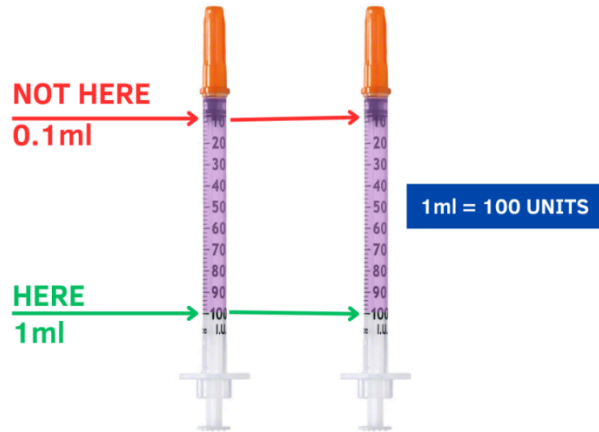
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### 25mg Vial

- Inject **2.5ml of bacteriostatic water** into the vial (2.5ml = 250 units). You will need to inject 2 full 1ml syringes and one 0.5ml syringe of water into the vial.

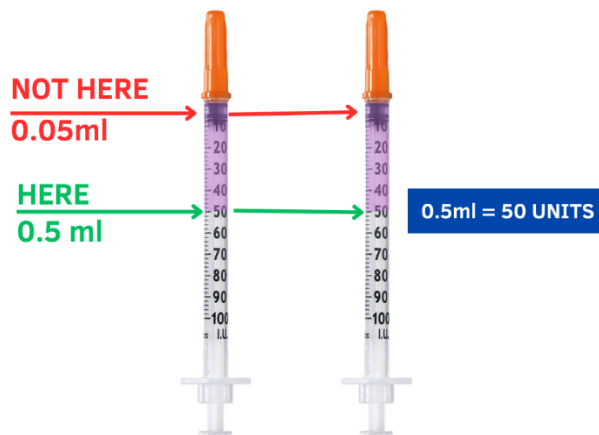
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**1 ml - 100 units (Not 10 UNITS)**



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**0.5ml - 50 units (Not 5 UNITS)**



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- See the **document** titled *“Reconstituting Medications in Powder Form”* in the Education Folder in the patient portal.
- See the following Instructional **videos** in the Education Folder in the patient portal:
  - *“Reconstituting Powdered Medications”*
  - *“Injection Video – Introduction”*
  - *“Injection Video – Drawing Up the Medication”*
  - *“Injection Video – Administering the Medication”*

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### Storage and Stability

- Vials are shipped as **lyophilized powder**, requiring no refrigeration during shipping.
- In Lyophilized Form:
  - Stable for up to 3 years in the freezer and 2 years in the refrigerator.
  - Protect from light.
- Once Reconstituted:
  - Stable for 6 weeks.
  - Must be refrigerated and kept away from light.
  - Avoid placing vials in the refrigerator door to prevent degradation from frequent temperature changes.

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### Important Disclosures

- These statements have not been evaluated by the US Food and Drug Administration (FDA).
- Not intended to diagnose, treat, cure, or prevent any disease.
- Compounded drugs and research peptides are not FDA-approved but are produced under strict quality control measures.

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### Quality Assurance

- All peptides are subjected to third-party testing with publicly available Certificates of Analysis (COA).
- Testing includes:
  - RP-HPLC (Reversed-Phase High-Performance Liquid Chromatography)
  - Mass Spectrometry (MS)
  - Sterility Testing
  - Additional tests meeting or exceeding U.S. Pharmacopeia (USP) and USP-National Formulary (NF) regulations.
- The manufacturer ensures quality, safety, and efficacy, complying with regulatory standards.