

Your guide to treatment with

Forzinity[®]



(elamipretide) injection

The first and only medication approved
by the FDA to treat muscle strength in
Barth syndrome

FORZINITY (elamipretide) is a once-daily injection indicated to improve muscle strength in individuals weighing at least 30 kg (~66 lb) who are affected by Barth syndrome.

This indication is approved under accelerated approval based on an improvement in knee extensor muscle strength, an intermediate clinical endpoint. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

You and/or your caregiver may have questions about how and when to take this medication.

This guide is designed to help you as you start your treatment journey with FORZINITY.

IMPORTANT SAFETY INFORMATION

What is FORZINITY used for?

FORZINITY is a prescription medicine used to improve muscle strength in adult and pediatric individuals living with Barth syndrome weighing at least 30 kg. The safety and effectiveness of FORZINITY have not been established in pediatric individuals weighing less than 30 kg.

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Please see additional Important Safety Information inside and Full [Prescribing Information](#).

Getting Started

Important things to know before your first injection

How to store FORZINITY after it arrives at your house

Once you receive your FORZINITY from the specialty pharmacy, store your new, unused vials upright in a refrigerator at a temperature between 36°F to 46°F (2°C to 8°C).



When you are ready to prepare your first injection using a new vial from the refrigerator, you will need to allow the vial to sit at room temperature for **at least 10 minutes**.

Once a vial has been used, it can remain at room temperature. You do not need to return the vial to the refrigerator between doses. Discard vial 8 days after opening. **DO NOT FREEZE VIALS.**

Like all medications, FORZINITY should be stored OUT OF THE REACH OF CHILDREN.

IMPORTANT SAFETY INFORMATION (cont'd)

What is FORZINITY used for? (cont'd)

The recommended dosage of FORZINITY in most affected individuals weighing at least 30 kg is 40 mg subcutaneously once daily. For individuals with reduced renal function, please have your doctor refer to the [Prescribing Information](#).

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Getting Started

Important things to know before your first injection (cont'd)

Take FORZINITY at the same time each day

FORZINITY is taken as a subcutaneous injection once a day. That means it needs to be injected between the skin and muscle around the same time each day to ensure the proper time between doses. If a dose is missed, a double dose should not be taken the next day. Take the prescribed amount at your next scheduled time.

Each vial contains enough solution for more than one dose. Discard the vial and any remaining solution 8 days after opening.

TIP:

Write the date that you open each vial (the first time you use it for injection) on the label and repeat this step for each new vial you open. For example:

- Vial 1 open date _____
- Vial 2 open date _____
- Vial 3 open date _____
- Vial 4 open date _____

Remember to always take medications exactly as instructed by your doctor.

IMPORTANT SAFETY INFORMATION (cont'd)

What is FORZINITY used for? (cont'd)

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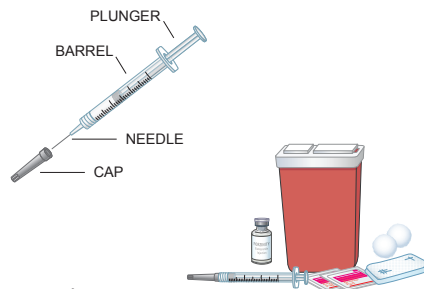


Instructions for injecting FORZINITY

STEP 1

Gather the supplies you need for your injection

- 1 vial of FORZINITY
- 1 new syringe with the needle attached
- 2 alcohol wipes
- Cotton ball or gauze pad
- Sharps disposal container



Before starting treatment, make sure to read the full Instructions for Use within the [Prescribing Information](#).

TIP:

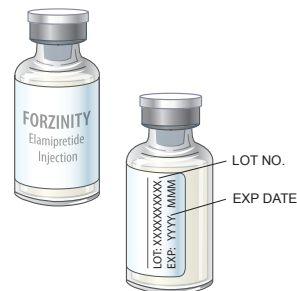
If you don't have a sharps container, you can use a household container that:

- Is made of heavy-duty plastic
- Has a tight-fitting, puncture-resistant lid that keeps sharps from coming out
- Stays upright and stable during use
- Is leak-resistant
- Is clearly labeled to warn that it contains hazardous waste

STEP 2

Check your FORZINITY vial

- Check that the vial says FORZINITY (elamipretide) and that the liquid looks clear and colorless to yellow. Do not use if the liquid is discolored or cloudy, or if the liquid has lumps, flakes, or particles
- Don't use it if the expiration or "discard after" date has passed
- Don't use it if the glass vial is cracked or the plastic cap on a new vial is broken or missing



IMPORTANT SAFETY INFORMATION (cont'd)

What should I tell my doctor before taking FORZINITY?

Before taking FORZINITY tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

You should also tell your doctor if you have or had:

- any allergies
- kidney problems

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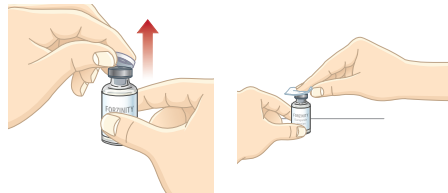


Instructions for injecting FORZINITY (cont'd)

STEP 3

Prepare the vial

- If you're using a new vial, remove and throw away the plastic cap
- Wipe the rubber top with an alcohol wipe to keep it clean before each injection

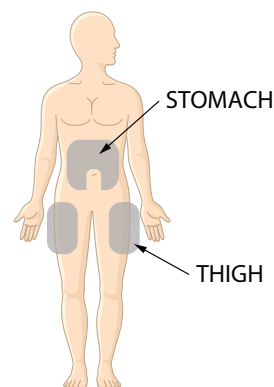


STEP 4

Prepare the injection site

FORZINITY is injected directly into a layer of fat under the skin.

- Choose an injection site on the stomach (at least 2 inches away from the belly button) or the outer part of the thigh
 - Pick a different spot each day
 - Don't inject in areas that are red, sore, bruised, hard, scarred, or have stretch marks, or where other medicines are injected
- Wipe the area with a new alcohol wipe and let it dry completely before injecting



TIP:

Keep track of your injection sites on a calendar or in a journal to make sure you use a different spot each day.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of FORZINITY?

- Injection site reactions: The most common side-effects or adverse reactions with FORZINITY are redness, swelling, pain, itching, bruising, or hives at the site of injection. These adverse reactions are referred to as injection site reactions.
- Allergic reactions. FORZINITY may cause allergic reactions, such as rash, small, raised skin bumps known as papular lesions, inflammation of the skin or eczematous dermatitis, as well as respiratory symptoms including cough. Stop using FORZINITY and get medical help right away if you develop any of the following symptoms of a severe allergic reaction:
 - swelling of your face, lips, mouth, or tongue
 - dizziness or fainting
 - trouble breathing or airway constriction
 - fast heartbeat or pounding in your chest
 - wheezing
 - sweating

These are NOT all of the possible side effects of FORZINITY.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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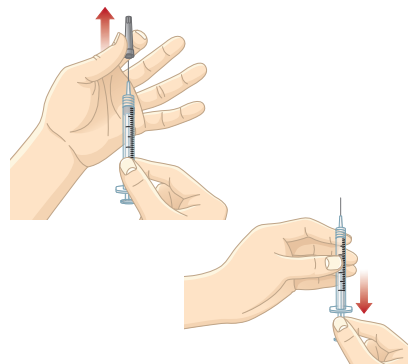


Instructions for injecting FORZINITY (cont'd)

STEP 5

Prepare the syringe

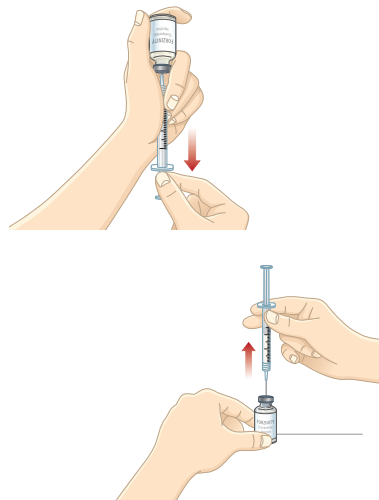
- Hold the syringe by the barrel and carefully remove the needle cap
- Pull back on the plunger to fill the syringe with air up to the prescribed dose
- Place the vial on a flat surface and insert the needle straight down through the center of the rubber top
- Gently push the plunger to inject all the air into the vial



STEP 6

Withdraw your dose from the vial into the syringe

- Keep the needle tip in the liquid, then turn the vial and syringe upside down
- Slowly pull back on the plunger to draw up the prescribed dose. Be careful not to pull the plunger all the way out
- Check for air bubbles
 - If you see large bubbles, gently tap the syringe until they rise to the top, then push the plunger slightly to send them back into the vial
 - If there are no large bubbles, gently pull back again to reach the full dose
- Turn the vial upright and, while holding it steady, pull the needle straight out



Note: Small air bubbles are normal, but large amounts may give you the wrong dose of FORZINITY.

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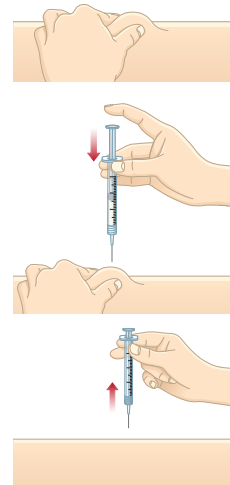


Instructions for injecting FORZINITY (cont'd)

STEP 7

Deliver the injection

- Gently pinch about 2 inches of skin between your thumb and pointer finger
- Hold the syringe at a 90° angle and insert the needle straight in
 - Push the needle in all the way, but don't press the plunger yet
- Once the needle is in, you can let go of the pinched skin
- Slowly press the plunger until the syringe is empty
- Remove the needle at the same angle, keeping the plunger pushed in
- If you notice a little bleeding, gently press a cotton ball or gauze pad on the spot



TIP:

Pinching the skin helps to make sure that you inject the medicine under the skin.

STEP 8

Safely dispose of used needle and syringe

- Don't put the needle cover back on or reuse the needle
- Never throw away needles or syringes in your household trash
- Place used needles and syringes in a sharps disposal container immediately after use



Work with your doctor to understand your or your child's symptoms and track progress together. Always talk with your doctor if you have any questions about treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

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Injection notes:

Type here...

Questions to ask my healthcare provider:

Type here...

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Mito Assist is here to help you every step of your FORZINITY journey

Access helpful resources, insurance support, financial assistance, and more



If requested by your doctor, a Visiting Nurse can come to your home or set up a telehealth visit to help you get started.

- Provides education for your subcutaneous injections



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How to reach your
Mito Assist team



1-833-458-9099
Available Monday – Friday,
8 AM – 7 PM CT

IMPORTANT SAFETY INFORMATION (cont'd)

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MAT-0075-1 07/2026

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