

INSTRUCTIONS FOR USE

STRENSIQ® [stren' sik]

(asfotase alfa)
injection, for subcutaneous use
vial

Read this “Instructions for Use” before you start using STRENSIQ and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Do not share your syringes or needles with anyone else. You may give an infection to them or get an infection from them.

Supplies needed to give your STRENSIQ injection (See Figure A):

- 1 or 2 STRENSIQ vial(s).
- 1 or 2 sterile disposable 1 mL syringes for injection with 25 to 29 gauge (G), ½ inch needles.
 - The use of two different gauge needles is recommended, a larger bore needle (e.g. 25 gauge) for withdrawal of the medication, and a smaller bore needle (e.g. 29 gauge) for the injection.
 - Always use a new syringe and needle for each injection.
- 2 alcohol wipes
- 1 gauze or cotton ball
- a clean flat surface, like a table
- 1 sharps container for throwing away used needles and syringes. See “Disposing of used needles and syringes” at the end of these instructions.

Figure A



Storing your STRENSIQ dose:

- Store STRENSIQ in the original carton in the refrigerator between 36°F to 46°F (2°C to 8°C) until you are ready to use it.
- Do not freeze your STRENSIQ vials. Do not use STRENSIQ if it has been frozen.
- Do not shake your STRENSIQ vials.
- Protect STRENSIQ from light until you are ready to use it.
- Do not use STRENSIQ after the expiration date printed on the carton.
- STRENSIQ vials are for 1 time use only. Throw away any unused STRENSIQ left in the vial.

Preparing your STRENSIQ dose and giving your STRENSIQ injection:

- Prepare a clean flat surface, like a table or counter top.
- Remove the unopened STRENSIQ vial(s) out of the refrigerator and allow it to sit at room temperature for at least 15 to 30 minutes. Injecting STRENSIQ when cold can make the injection feel uncomfortable.
 - Do not warm STRENSIQ in any way other than letting it sit at room temperature (for example, do not warm it in a microwave or in hot water).
- Gather all the supplies you will need to give your STRENSIQ injection.
- Wash your hands with soap and water.
- Utilize STRENSIQ within 3 hours after removing it from the refrigerator.
- Inject STRENSIQ exactly as your healthcare provider has shown you.

Step 1:	Check the liquid in the STRENSIQ vial. STRENSIQ liquid should look clear or slightly yellow and may have a few small white particles in
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	it. Do not use it if the liquid is discolored or contains any lumps or large particles in it. Throw it away and get a new vial.	
Step 2:	Using your thumb, flip the plastic cap off the STRENSIQ vial.	
Step 3:	Remove the larger bore needle (e.g., 25 G) from the package. Pick up the syringe and place the needle on the tip of the syringe. Push down and twist the needle onto the syringe until it is tight.	
Step 4:	Hold the syringe with the needle pointing up and pull back the plunger until the top of the plunger reaches the line for your prescribed dose.	
Step 5:	Pull the cap straight off of the needle. <ul style="list-style-type: none"> • Do not touch the needle or let the needle touch any surface. 	
Step 6:	Hold the STRENSIQ vial firmly on a flat surface, then push the needle through the rubber stopper of the STRENSIQ vial.	
Step 7:	Keeping the needle in the STRENSIQ vial, lift the vial and turn it upside down with the needle pointing toward the ceiling. Slowly push the plunger all the way in.	
Step 8:	With the needle tip still in the liquid, slowly pull back the plunger until the top of the plunger reaches the line for your prescribed dose. Do not pull the needle out of the STRENSIQ vial. Slowly push the plunger up until the top of the plunger reaches the line for your prescribed dose. <ul style="list-style-type: none"> • Check the syringe to make sure that you have the right dose. 	

Step 9: Turn the STRENSIQ vial upright and pull the syringe straight out of the vial's rubber stopper.

- **Do not** touch the needle or allow the needle to touch any surface.

Carefully remove the larger bore needle (e.g., 25 G) you withdrew the STRENSIQ dose with and dispose of properly (as noted at the end of these instructions).

Replace with a new, smaller bore needle (e.g., 29 G) prior to injection.

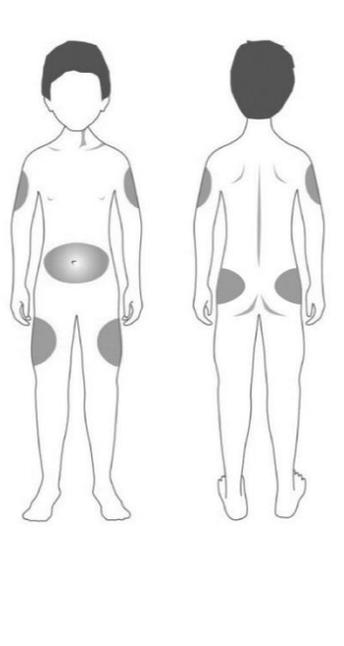


Step 10: Hold the syringe with the needle pointing up and tap the barrel of the syringe with your finger to remove any air bubbles.



Step 11: Choose your injection site. STRENSIQ is injected under the skin (subcutaneously) of your stomach-area (abdomen), upper arms, upper legs, or buttocks.

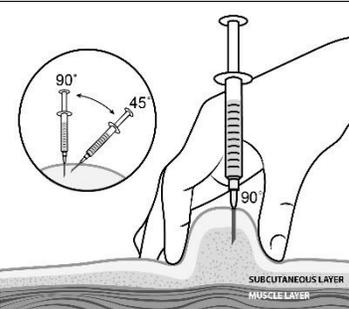
- **Do not** inject STRENSIQ into the buttocks for infants.
- **Change (rotate) your injection site with each injection.** Do not use the same injection site for each injection.
- **Do not** inject STRENSIQ into skin that is red, hot, or swollen.
- Wipe your skin with an alcohol wipe. Let the site dry before you inject your dose.



Step 12: Pinch the skin. Hold the syringe at a 90° angle (straight up and down) and insert the needle into your skin. For patients with little fat, hold the syringe at a 45° angle and insert the needle into your skin.




Step 13: Push the plunger slowly and steadily all the way in to give your dose.



Step 14: Pull the needle out of your skin.

- If you see blood after you take the needle out of your skin, press your injection site with a piece of gauze or alcohol wipe.
- **Do not** recap the needle. Recapping the needle can lead to a needle stick injury.

If you need a second injection for your prescribed dose, get another STRENSIQ vial and repeat steps 1 through 14.



Disposing of used needles and syringes:

- Put your used needles in a FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) loose needles and syringes in your household trash.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid,
 - without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

Keep STRENSIQ and all medicines, needles and syringes out of the reach of children.

This "Instructions for Use" has been approved by the U.S. Food and Drug Administration.

Manufactured by:

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U.S. License Number: 1743

Approved: 6/2020