INJECTION GUIDE
For parents and caregivers of children taking Strensiq®

40 mg/mL solution for injection
- 18 mg/0.45 mL
- 28 mg/0.7 mL
- 40 mg/1.0 mL

100 mg/mL solution for injection
- 80 mg/0.8 mL

Please see accompanying full Prescribing Information, including FDA-approved Patient Labeling.
Introduction

This injection guide is designed to assist parents and caregivers of children who have been prescribed Strensiq®.

Strensiq is indicated for the treatment of people with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP).

Inside you will find detailed instructions and diagrams that describe how to help choose your child’s injection site, give the injection, and record it. This guide is intended to supplement the training given by your child’s healthcare provider.

It is important to use Strensiq as described in the Patient Prescribing Information and Instructions for Use, and as instructed by your child’s doctor, nurse, or pharmacist.

Before starting Strensiq, speak to your child’s doctor about how often Strensiq should be injected. Always give the exact dose of Strensiq prescribed by your child’s doctor.

OneSource™

As your child is getting started on Strensiq, Alexion’s OneSource program is here to help. OneSource is made up of a team of Alexion nurse case managers who are registered nurses with healthcare and insurance experience. Whether you want to learn more about HPP or have questions about treatment with Strensiq, OneSource is only a phone call away.

Call 1-888-765-4747 to enroll in OneSource today.

Please see Important Safety Information on page 5.
Storage and handling

Do not inject your child with Strensiq® until you have had proper training from your child’s doctor, nurse, or pharmacist.

- Use Strensiq exactly as your child’s healthcare provider tells you
- Store Strensiq in the original carton in the refrigerator between 36°F and 46°F (2°C to 8°C) until you are ready to use it
- Protect Strensiq from light until you are ready to use it
- Use Strensiq within 1 hour after you remove it from the refrigerator
- DO NOT freeze Strensiq or inject Strensiq that you suspect has been frozen
- DO NOT shake Strensiq vials
- If you suspect the liquid in the vial has been contaminated, DO NOT use it. Contact your child’s healthcare provider for advice
- Do not use Strensiq after the expiration date printed on the carton
- Strensiq vials are for one-time use only. Throw away any unused Strensiq left in the vial

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

Reporting side effects

Speak with your child’s doctor, nurse, or pharmacist to report any side effects or to discuss all the possible side effects for Strensiq. You may report side effects directly to the US Food and Drug Administration (FDA) at 1-800-FDA-1088. By reporting side effects, you can help provide more information on the safety of Strensiq.

For detailed information on Strensiq, please see accompanying full Prescribing Information, including FDA-approved Patient Labeling.
What is Strensiq®?

Strensiq is a prescription medicine that works by replacing alkaline phosphatase (ALP). It is used to treat people with perinatal/infantile- and juvenile-onset HPP.

What should you tell your healthcare provider?

Before you start Strensiq, healthcare providers need to know if your child is

- Allergic to asfotase alfa or any of the ingredients in Strensiq
- Pregnant or planning to become pregnant. It is not known if Strensiq will harm unborn babies
- Breastfeeding or planning to breastfeed. It is not known if Strensiq passes into breast milk. Women being treated with Strensiq should speak with their doctors about the best way to feed their infant children

How is Strensiq dosed?

The amount of Strensiq given is determined based on your child’s weight. The doctor will determine the amount of Strensiq your child should receive.

The doctor will decide if your child should receive 1 mg/kg of Strensiq, 6 times per week, or 2 mg/kg of Strensiq, 3 times per week (totaling 6 mg/kg of Strensiq per week).

The maximum volume of medication per injection should not exceed 1 mL. If more than 1 mL is required for each dose, split the volume equally between 2 syringes and administer 2 injections. When administering the 2 injections, use 2 separate injection sites.

Tips for injecting Strensiq

- Carefully read the Patient Labeling and Instructions for Use before your child starts using Strensiq and each time you get a refill
- Strensiq is given as an injection under the skin (called a subcutaneous injection)
- Strensiq is injected under the skin (subcutaneously) in areas with a substantial amount of fat. It can be injected under the skin of the stomach, upper arms, or upper legs
- Choose a different area each time you inject your child to help avoid irritation and reactions at the injection site
- Do not inject Strensiq into skin that is red, hot, or swollen
- Always use the exact dose of Strensiq prescribed by your child’s doctor. Before starting Strensiq, the doctor will speak with you about how often Strensiq should be injected

Talk to your child’s doctor, nurse, or pharmacist about the best areas to inject Strensiq.
Injecting Strensiq®

Refrigerate Strensiq until you are ready to use it. You should use Strensiq within 1 hour of removing it from the refrigerator.

Please remember: each Strensiq vial is for single use only and should be punctured only once. Used vials must be discarded at the end of each injection.

Be sure to wash your hands with soap and water prior to preparing and giving your child’s injection.

Place all items needed for your child’s Strensiq injection on a clean, flat surface. Items should include:
- Vial(s) for injection
- Sterile syringe and needle
  - 1-mL syringe(s) for injection with one-half inch, 25- to 29-gauge injection needle(s)
- Sharps container (for throwing away used needles and syringes)*
- Alcohol wipes
- Gauze or cotton ball

Choose an injection site (see diagram on page 7) and prepare it according to the advice given by your child’s doctor, nurse, or pharmacist.

Tip: Remember to record each injection in the injection diary (or other recording means).

*OneSource can provide a sharps container for people taking Strensiq. Call 1-888-765-4747 to sign up and learn more.

Injecting Strensiq (cont’d)

1. Check the liquid in the vial. It should look clear or slightly yellow and may have a few small white particles in it. Do not use if the liquid is discolored or contains any lumps or large particles in it. Throw it away and get a new vial.
2. Using your thumb, flip the plastic cap off the vial.
3. Remove the needle 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.
4. Hold the syringe with the needle pointing up and pull back the plunger until the top of the plunger reaches the line for the prescribed dose.
5. Pull the cap straight off of the needle.
   **Do not** touch the needle or let the needle touch any surface.
6. Hold the vial firmly on a flat surface, then push the needle through the rubber stopper of the vial.

Please see Important Safety Information on page 5.
Injecting Strepsiq® (cont’d)

7. Keeping the needle in the vial, lift the vial and turn it upside down with the needle pointing toward the ceiling. Slowly push the plunger all the way in.

8. With the needle tip still in the liquid, slowly pull back the plunger until the top of the plunger reaches the line slightly past the line for the prescribed dose.
   Do not pull the needle out of the vial. Slowly push the plunger up until the top reaches the line for the prescribed dose.
   • Check the syringe to make sure you have the right dose.

9. Turn the 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.

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

11. Choose the injection site. Strepsiq is injected under the skin of your child’s stomach area, upper arms, or upper legs.
   • Change (rotate) the injection site with each injection. Do not use the same injection site for each injection.
     • Do not inject Strepsiq into skin that is red, hot, or swollen.
     • Wipe the skin with an alcohol wipe. Let the site dry before you inject the dose.

12. Pinch the skin. Hold the syringe at a 90° angle (straight up and down) and insert the needle into the skin. If your child does not have much fat, hold the syringe at a 45° angle and insert the needle into the skin.
Injecting Stremsiq® (cont’d)

13. Push the plunger all the way in to give your child’s dose.

14. Pull the needle out of the skin.
   - If you see blood after you take the needle out of the skin, press the 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 child’s prescribed dose, get a new needle and another vial of Stremsiq, and repeat steps 1 through 14.

Dispensing of used needles and syringes

Put the used needles in an FDA-cleared sharps disposal container immediately after use. Do not throw away (dispose of) loose needles and syringes in your household trash.

If you do not have an 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
   • 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 on sharps disposal, go to the FDA’s website: 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 used sharps disposal container.

Remember, OneSource provides sharps disposal containers and a convenient mail-back program to help dispose of needles. Call 1-888-765-4747 to enroll in OneSource.

Please see Important Safety Information on page 5.
Traveling with Strensiq®

Before you go

- Have your child’s doctor, nurse, or pharmacist calculate how many vials, syringes, and needles you will need for your trip. Take more than you need in case you and your child are away for longer than expected.
- Remember to bring along your sharps disposal container.
- Check to ensure that your travel destination has a refrigerator that you can use to store Strensiq.
- You should keep Strensiq cold while traveling. You may want to store it with an ice pack in order to keep Strensiq at the right temperature (36°F to 46°F [2°C to 8°C]). Do not freeze. (Ensure that ice packs are not in direct contact with your medication)
- If you have any concerns about traveling, talk to your child’s doctor, nurse, or pharmacist.

When flying

- Always travel with Strensiq in your carry-on luggage. Do not store Strensiq in your checked luggage.
- Your child’s doctor can provide a letter explaining that your child needs to travel with this medication.
- Prior to your trip, check with your airline or the airports you are traveling through for any specific rules about syringes and needles.

Resources and support

Starting a new medication can be difficult. Resources are available to help you get connected with the HPP community, assist with treatment support, and help you learn more about HPP and treatment with Strensiq.

- **Strensiq.com**
  Learn more about Strensiq and OneSource.

- **OneSource**
  As your child is getting started on Strensiq, OneSource offers personalized support. After signing up, you’ll be matched with an Alexion nurse case manager who can help answer questions about HPP and assist with your child’s treatment with Strensiq.

  OneSource provides:
  - Help with your child’s disease and treatment.
  - Connections with other people living with HPP.
  - Information on co-pay support and financial assistance programs.
  - Treatment support from Alexion nurse case managers.
  - Information on Alexion Access Foundation for eligible patients without insurance.
  - Specialized medication refrigerator to help store Strensiq and track injections.
  - Supplemental in-home injection training by trained professionals.
  - A convenient mail-back program to help dispose of needles.

Call 1-888-765-4747 to enroll in OneSource today.

If you have any questions or concerns about Strensiq, speak with your child’s doctor, nurse, or pharmacist.

You may report side effects to the FDA at 1-800-FDA-1088.

Please see Important Safety Information on page 5.