INJECTION GUIDE
Parents/Caregivers with Infant Patients

40 mg/ml solution for injection
18 mg/0.45 ml  28 mg/0.7 ml  40 mg/1 ml

100 mg/ml solution for injection
80 mg/0.8 ml

asfotase alfa
Introduction

This Injection Guide is for the parents and caregivers of infant patients with paediatric-onset hypophosphatasia who would benefit from long-term enzyme replacement therapy and have been prescribed Strensiq®.

The guide gives detailed instructions, with clear diagrams, on how to choose the injection site and how to carry out and record the injection of your infant or child.

This guide is designed as a support document to the training given by your healthcare professional.

Please contact your healthcare professional if you have any questions.
Important Information

Do not inject your infant or child with Strensiq® until you have had proper training from a healthcare professional.

• Before starting, check the expiry date of Strensiq®. DO NOT use if it has expired.
• Always use a new vial and carefully examine the liquid to make sure it is clear and contains no particles.
• If you suspect that the liquid in your vial has been contaminated, DO NOT use it and contact your healthcare professional for advice.
• Always use the specific dose (in number of milligrams) that has been prescribed by your doctor.
• Vials are for single use and should only be punctured once. Used vials must be discarded at the end of the injection.
• Syringes and needles are for single use only and should be handled with care. Keep them out of reach from children and dispose of them safely in a special sharps container. Needles and syringes must not be mixed with normal household rubbish.
• Store your Strensiq® vials in the refrigerator at a temperature between 2°C and 8°C. DO NOT put Strensiq® in or near the freezer compartment and never inject Strensiq® that you know, or suspect, has been frozen.
• Store your Strensiq® in the original package in order to protect the medication from light.

For detailed information on Strensiq® please refer to the Patient Information Leaflet which you can find in the Strensiq® package.

Warnings and Precautions

• If your infant or child is treated with Strensiq®, they may experience a reaction at the injection site during the injection of the medicine or during the hours following the injection.
• Patients receiving Strensiq® have had life threatening allergic reactions similar to anaphylaxis requiring medical treatment. Patients who experienced anaphylaxis-like symptoms had difficulty breathing, choking sensation, nausea, swelling around the eyes, and/or dizziness. The reactions occurred within minutes after injecting Strensiq® in patients, and can occur in patients who had been taking Strensiq® for a period of time (e.g. more than one year).
• If your infant or child experiences any of these symptoms, discontinue Strensiq® and seek medical help immediately.
• If your infant or child experiences an anaphylactic reaction, or an event with similar symptoms, your doctor will discuss with you the next steps and the possibility to restart Strensiq® under medical supervision. Always follow the instructions provided by your doctor.
• When injecting regularly, the position on the body where the injections are given should be changed to a different site with each injection, as this may help reduce pain and irritation.
• Areas with a substantial amount of fat below the skin are the most suitable areas to inject (see diagram on page 7). Please discuss with your healthcare professional the best sites to inject your infant or child.
What is Strensiq®?
Strensiq® is a medication designed as a long-term enzyme replacement therapy in patients with paediatric-onset hypophosphatasia. It is administered subcutaneously, under the skin.

How does my infant or child get started on Strensiq® therapy?
Strensiq® must be prescribed by your infant or child’s doctor.
Your healthcare professional will advise you on the range of educational materials available to help with the therapy. This injection guide and the available animated instructions can help support you when learning how to inject your infant or child. The animated instructions can be accessed by scanning the QR Code on the Patient Information Leaflet.

What dose of Strensiq® is used?
Once Strensiq® has been prescribed for your infant or child you will need to administer the drug according to the specific dose (in number of milligrams) that has been prescribed by your doctor.

The dose you administer is based on your infant or child’s body weight. The correct dose will be calculated by your doctor and consists of a total of 6 mg per kg of body weight per week of Strensiq®, administered by subcutaneous injection. You may receive either 1 mg/kg of Strensiq® six times per week or 2 mg/kg of Strensiq® three times per week depending on the recommendation of your doctor.

For example, if the body weight of your infant or child is 6 kg, he or she will receive 6 mg six times per week or 12 mg three times per week.

The maximum volume of medication per injection should not exceed 1ml. If more than 1ml is required, multiple injections may be administered, one after another.

How is Strensiq® administered?
Strensiq® is administered either three or six times per week as a subcutaneous injection into the fatty layer just below the skin. This is called the subcutaneous layer and it is just above the muscle.

There are specific areas of the body suitable for giving subcutaneous injections to infants and children, shown on the diagram below. As a general rule, these areas are those with a substantial amount of fat below the skin. The thighs and abdomen tend to be the most suitable for infants and children.

When injecting regularly, the position on the body where the injections are given should be rotated, as this may help reduce pain and irritation.

As your infant or child grows, other areas may become suitable, such as the arms and buttocks. Please discuss with your healthcare professional the best sites for your infant or child.

Please remember, this guide is designed as a support document to the training given by your healthcare professional.
Injecting Strensiq®

Before you begin, take your vial(s) out of the refrigerator. The vial(s) should be allowed to reach room temperature and administered within 1 hour.

Please remember your vials are for single use and should only be punctured once. Used vials must be discarded at the end of the injection.

Wash your hands thoroughly with soap and water.

Place all the items you will need on a clean area where you will not be disturbed. These should include:

- Your vial(s) for injection
- Your syringe(s)
- One larger bore syringe needle (e.g. 25G)
- One smaller bore syringe needle (e.g. 27 or 29G, with length appropriate for subcutaneous injection)
- Alcohol swabs (if required)
- Gauze or cotton wool
- Your sharps container*
- Plaster or adhesive bandage (if required)
- Injection diary (or other recording means)

Choose the injection site (see diagram on page 7) and prepare it according to the advice given by your healthcare professional.

*Your healthcare professional will advise on how you can obtain a sharps container and will also advise you on the disposal procedure.
Invert the vial and syringe. With the needle in the solution, pull the plunger to withdraw the correct dose into the syringe.

Before removing the needle from the vial, check the syringe for air bubbles.

In the event that bubbles appear in the syringe, hold the syringe with the needle pointing upwards and gently tap the side of the syringe until the bubbles rise to the top.

Once all the bubbles are at the top of the syringe, gently push on the plunger to force the bubbles out of the syringe and back into the vial.

After removing the bubbles, check the dose of medication in the syringe to be sure you have drawn up the correct amount.

Remove the needle from the vial.

Remove the larger bore needle pushing down and turning counterclockwise and dispose of it in your sharps container.

Place a smaller bore needle (e.g. 27 or 29G) on the filled syringe and with the protective cap on, push down and turn clockwise the needle onto the syringe until it is tight. Pull the cap straight off the needle and dispose of it in your sharps container.

Hold the syringe with the needle pointing up and tap the barrel of the syringe with your finger to remove any air bubbles. You are now ready to inject the correct dose.
Injecting Strensiq®

10. Your infant or child should be held firmly in a comfortable position.

Your healthcare professional will advise you on the best position to hold your infant or child for the chosen injection site.

11. Gently pinch the skin of the chosen injection area (in this case the infant or child’s thigh) between your thumb and index finger.

12. Holding the syringe like a pencil or a dart, insert the needle into the raised skin so it is at an angle of between 45° and 90° to the skin surface. For small children who have little subcutaneous fat or thin skin, a 45° angle may be preferable.

13. While continuing to hold the skin, push the syringe plunger to inject the medication while counting slowly to 10.

Remove the needle, release the skin fold and gently place a piece of cotton wool or gauze over the injection site for a few seconds.

14. Dispose of your syringe and used vial into your sharps container.

Your vials are for single use and should only be punctured once.

Place a small plaster or adhesive bandage over the injection site, if necessary.

15. Record all details of the injection in your injection diary or using other means.

It is recommended that you note:
- where you injected
- the dose injected
- any injection reactions

If you have any concerns about injection reactions, preparing or administering medication for your infant or child, discuss them with your healthcare professional.
Storing and Travelling with Strensiq®

Storing your Strensiq® vials

- Store your Strensiq® vials in the refrigerator at a temperature between 2°C and 8°C. DO NOT put Strensiq® in or near the freezer compartment and never inject Strensiq® that you know, or suspect, has been frozen.
- Store your Strensiq® in the original package in order to protect the medication from light.
- Before starting, check the expiry date of Strensiq® which you will find on the vial label. DO NOT use if it has expired.

Travelling with your Strensiq® vials

- Calculate how many vials you will need for your trip. Take some extra in case you are away for longer than expected.
- Remember to take your sharps container and some extra syringes. It is recommended that you carry your supplies as hand luggage.
- Check to ensure that your travel destination has refrigeration that you can use.
- It is recommended that you carry your vials in a cool bag when you travel. The bag should contain cool blocks to help keep your vials at the correct temperature.
- Keep the cool blocks in your freezer so that they are ready for use when you travel. Ensure that the frozen cool blocks are not in direct contact with your medication.

Travelling by air

- It is recommended that you carry your medication and supplies as hand luggage.
- It may be advisable to carry a letter from your infant or child’s doctor explaining that you need to travel with your medication.

Storing and Travelling with Strensiq®

- Check with your airline, or the airports you are travelling through, for any specific rules for persons carrying injectable medication and associated accessories.
- If you have any concerns about travelling, discuss them with your healthcare professional.

Local Contacts

Provided as a patient educational service by Alexion Pharma UK.

For more information please see:

www.asfotasealfa-patienteducation.co.uk

Reporting of side effects

If your infant or child experiences any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this guide.

Adverse events (side effects to the drug) should be reported.

Reporting forms and information can be found at:

http://www.mhra.gov.uk/yellowcard (UK)
http://www.hpra.ie (Ireland)

Adverse events and product complaints should also be reported to: Alexion Pharma UK on 0800 3213902 Ireland Freephone 1 800 936 544 or by email to uk.adverseevents@alexion.com

By reporting side effects you can help provide more information on the safety of this medicine.