Strensiq® (asfotase alfa) for injection | 40 mg/mL

MANAGING INJECTION-SITE REACTIONS

STRENSIQ® (asfotase alfa) INDICATION & IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

INDICATION

What is STRENSIQ?
STRENSIQ is a prescription medicine used to treat people with perinatal, infantile, and juvenile onset hypophosphatasia (HPP).

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about STRENSIQ?
STRENSIQ may cause serious side effects, including severe allergic (hypersensitivity) reactions. Allergic reactions are common with STRENSIQ treatment and can be severe and life-threatening. Severe allergic reactions have happened in some people within minutes after receiving STRENSIQ and more than 1 year after starting treatment with STRENSIQ. Stop using STRENSIQ and go to the nearest hospital emergency room right away if you or your loved one get any of the following signs and symptoms of a serious allergic reaction:

- difficulty breathing
- choking sensation
- swelling of your eyes, lips, or tongue
- dizziness
- nausea or vomiting
- fever
- headache
- sweating
- feeling irritable
- chills
- skin redness
- skin rash or hives
- itching or numbness of the tongue, lips, cheeks, or gums

Please see additional Important Safety Information on pages 4 and 5, and full Prescribing Information for STRENSIQ (asfotase alfa), including Boxed WARNING regarding severe allergic (hypersensitivity) reactions.

ABOUT INJECTION-SITE REACTIONS

A local skin injection-site reaction is one of the most common side effects of STRENSIQ® (asfotase alfa). While these reactions may be temporarily unpleasant, in most cases, they can be manageable and may resolve within a week.

Talk to your doctor about what treatment-related reactions look like for you or someone you care for.

Injection-site reactions may appear as:

- **Red skin patches**
- **Bruising**
- **Color change**
- **Pain**
- **Itching**
- **Thinning**
- **Swelling**
- **Pits**
- **Bumps**
- **Hardening/ thickening of the skin**

INJECTION TIPS

Follow these tips to reduce the chance of experiencing injection-site reactions.

Remove STRENSIQ from the refrigerator 15 to 30 minutes prior to your injection to allow it to come to room temperature. Be sure to use STRENSIQ within 3 hours of removing it from the refrigerator. Do not warm STRENSIQ in any other way (for example, do not warm it in a microwave or in hot water).

Note: Vial contents should appear clear or slightly yellow and may have small white particles. Do not use it if the liquid is discolored or contains any lumps or particles in it. Throw it away and get a new vial.

Wash your hands and properly clean your chosen injection site with an alcohol wipe.

Note: Let the alcohol dry before giving the injection.

Rotate the injection site with each injection. When administering 2 separate injections for your prescribed dose, use 2 separate injection sites.

Note: Injection sites include stomach, back of the upper arms, front of the upper legs (thighs), and buttocks. Do not inject STRENSIQ into the buttocks for infants.

Do not inject in red, hot, or swollen areas, and avoid areas that might be irritated from a previous injection.

HOW TO TALK WITH YOUR DOCTOR

It may help to take a photo of the injection-site reaction(s) to show your or your loved one's doctor. You can also describe it using these prompts:

- Where is the reaction?
- What does it feel like?
- How soon after an injection do you notice it?
- How large is it?
- How long does it typically last before going away?

Remember to use STRENSIQ exactly as instructed by your doctor.

ONESOURCE®
Personalized Patient Support from Alexion

For additional information and treatment support, call OneSource™ at 1-888-765-4747 or visit AlexionOneSource.com.

The content included herein is not intended to be a substitute for professional medical advice or treatment. Always seek the advice of a physician or other qualified healthcare provider with any questions you may have about a medical condition.

STRENSIQ® (asfotase alfa) INDICATION & IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING (cont'd)

What are the other possible side effects of STRENSIQ? STRENSIQ may cause other serious side effects, including:

- **skin thickening or pits at the injection site (lipodystrophy).** Lipodystrophy is common and has happened after several months in people treated with STRENSIQ.
- **calcium build-up in the eyes and kidneys.** People with HPP are at increased risk for developing calcium build-up in the body. Calcium build-up in the eyes and kidneys has happened and is a common side effect of STRENSIQ. Calcium build-up in the eyes and kidneys may also happen in people with HPP who are not treated with STRENSIQ. Your healthcare provider should check your eyes and kidneys before and during treatment with STRENSIQ.
- **immune-related effects.** You may develop antibodies during treatment that may decrease how well STRENSIQ works. Tell your healthcare provider right away if you get worsening symptoms of HPP including: difficulty breathing, difficulty walking, feeling tired, bone pain, stiff joints, or loss of appetite.

The most common side effects of STRENSIQ include local skin injection site reactions such as skin redness, bruising, color change, pain, itching, hardening of the skin (induration), swelling, and bumps. These are not all the possible side effects of STRENSIQ. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects.

You will begin receiving STRENSIQ under the supervision of a healthcare provider. Tell your healthcare provider about all your medical conditions, including if you:

- have had an allergic reaction to STRENSIQ.
- are pregnant or plan to become pregnant. It is not known if STRENSIQ will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if STRENSIQ passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you use STRENSIQ.

STRENSIQ® (asfotase alfa) INDICATION & IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING (cont'd)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

There is a registry for people who use STRENSIQ. The purpose of this registry is to collect information about HPP and about what happens when you use STRENSIQ for a long time. For more information about this registry, talk with your healthcare provider or go to www.hppregistry.com

To report SUSPECTED SIDE EFFECTS, contact Alexion Pharmaceuticals, Inc. at 1-844-259-6783 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

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