

PATIENT INFORMATION
STRENSIQ® [stren sik]
(asfotase alfa)
injection, for subcutaneous use

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 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

What is STRENSIQ?

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

Before using STRENSIQ, tell your healthcare provider about all of 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.

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.

How should I use STRENSIQ?

- Use STRENSIQ exactly as your healthcare provider tells you to.
- You will begin receiving STRENSIQ under the supervision of a healthcare provider.
- **See the “Instructions for Use” at the end of the Patient Information for instructions about:**
 - **How to prepare and inject STRENSIQ**
 - **How to properly throw away (dispose of) any unused STRENSIQ**
 - **How to dispose of used syringes and needles.**
- Your healthcare provider will tell you how much STRENSIQ to use and when to use it.
- Your healthcare provider may change your dose, if needed.

What are the possible side effects of STRENSIQ?

STRENSIQ may cause serious side effects, including:

- **severe allergic (hypersensitivity) reactions.** See “What is the most important information I should know about STRENSIQ?”

- **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 your 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
 - 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 of the possible side effects of STRENSIQ. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of STRENSIQ.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use STRENSIQ for a condition for which it was not prescribed. Do not give STRENSIQ to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about STRENSIQ that is written for health professionals.

What are the ingredients in STRENSIQ?

Active ingredient: asfotase alfa.

Inactive ingredients: dibasic sodium phosphate, heptahydrate; monobasic sodium phosphate, monohydrate and sodium chloride.

Manufactured by: Alexion Pharmaceuticals, Inc., Boston, MA 02210 USA

U.S. License Number: 1743

For more information, go to www.strensiq.com or call 888-765-4747.