

Patient Information

STRENSIQ® (stren' sik)

(asfotase alfa) injection, for subcutaneous use

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:

- are allergic to asfotase alfa or any of the ingredients in STRENSIQ. See the end of this leaflet for a complete list of ingredients in STRENSIQ.
- are pregnant or planning 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 medications 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?

- See the "Instructions for Use" that come with STRENSIQ for detailed instructions about the right way to use STRENSIQ.
- Use STRENSIQ exactly as your healthcare provider tells you to.
- 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.
- Change (rotate) your injection site with each injection. **Do not** use the same injection site for each injection.

What are the possible side effects of STRENSIQ?

STRENSIQ may cause serious side effects, including:

- **serious allergic (hypersensitivity) reactions.** Serious allergic reactions have happened in some people who use STRENSIQ. Stop using STRENSIQ and go to

the nearest hospital emergency room right away if you have any of the signs and symptoms of a serious allergic reaction including:

- difficulty breathing
- swelling of your eyes, lips or tongue
- hives
- feeling faint
- nausea or vomiting
- dizziness
- itching of lips, tongue or throat
- choking sensation

- **skin thickening or pits at the injection site (lipodystrophy).** Lipodystrophy at the injection site has happened several months after using STRENSIQ.
- **calcium build up in your eyes and kidneys.** Your healthcare provider should check your eyes and kidneys while you use STRENSIQ.

The most common side effects of STRENSIQ include local skin injection site reactions (including skin red patches, bruising, color change, pain, itching, thinning, swelling, pits, and bumps) and calcium build up in your eyes and kidneys.

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 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 healthcare 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., New Haven, CT 06510 USA U.S. License Number: 1743

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

This Patient Information has been approved by the U.S. Food and Drug Administration

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