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To Whom It May Concern:

This patient is currently being treated with STRENSIQ[®] (asfotase alfa), a therapy manufactured by Alexion Pharmaceuticals, Inc. and distributed by PANTHERx Rare.



STRENSIQ is administered via subcutaneous injection, and is packaged in single-dose vials containing either 18mg/0.45 mL, 28mg/0.7 mL, 40 mg/mL, or 80 mg/0.8mL per vial. **STRENSIQ is neither a narcotic nor psychotropic medication. Needles and syringes are required for self-/caregiver-administration of STRENSIQ.** STRENSIQ is for individual use and not for resale.



STRENSIQ must be kept at a stable, cold temperature between 2-8°C (36°F-46°F) and protected from light to ensure medication stability. STRENSIQ is to be carried in a cooler specifically designed to maintain the appropriate temperature. Please note that, due to the temperature sensitivity of STRENSIQ, <u>the cooler</u> containing the medication must be stored in the cabin of the airplane and not stored with checked luggage. Failure to maintain the proper temperature of STRENSIQ may cause it to lose stability, potentially rendering it ineffective.

For questions about this letter, please call PANTHERx Rare Pharmacy at 1-855-726-8479.

Respectfully,

STRENSIQ RxARECARE[™] Team PANTHERx Rare Pharmacy Email: strensiq@pantherxrare.com Phone: 1-855-726-8479

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

- sweating
- feeling irritable
- chills
- skin redness
- skin rash or hives
- itching or numbness of the tongue, lips, cheeks, or gums

headache

Please see full <u>Prescribing Information</u> and <u>Patient Information</u> for STRENSIQ (asfotase alfa), including Boxed WARNING regarding severe allergic (hypersensitivity) reactions.



Defining Rare Pharmacy®

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

IMPORTANT SAFETY INFORMATION (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.

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 <u>www.hppregistry.com</u>

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

INDICATION

What is STRENSIQ?

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

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