An Overview of Access and Support Resources

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

Alexion is committed to providing access and educational support to physicians and their offices for patients who have been prescribed STRENSIQ. This overview includes the important steps in the STRENSIQ access process and the resources available. It is intended for educational purposes only and does not guarantee coverage or access to treatment.

1 STRENSIQ is Prescribed

You have diagnosed a patient with perinatal/infantile- or juvenile-onset hypophosphatasia (HPP) and have prescribed STRENSIQ. Now what?

2 Benefit Investigation

After you have prescribed STRENSIQ, Alexion's contracted specialty pharmacy, PANTHERx, will conduct a benefit investigation with the patient's health plan.

3 Prior Authorization

Once the benefit investigation is complete, PANTHERx will share the health plan's prior authorization (PA) requirements with you. Each patient will have different requirements based on their unique health plan.

4 Prior Authorization Approval

Once all PA requirements have been completed and submitted to the patient's health plan, the PA will either be approved or denied. If approved, PANTHERx will ship STRENSIQ to the patient. If denied, you will need to determine the reason and the best course of action specific to your patient's health plan.

5 Reauthorization

After your patient has begun therapy on STRENSIQ, health plans will require a reauthorization. Reauthorization timelines and requirements will vary based on each patient's unique health plan.

INDICATION

STRENSIQ® (asfotase alfa) is indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP).

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

Patients treated with enzyme replacement therapies have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy.

Initiate STRENSIQ under the supervision of a healthcare provider with appropriate medical monitoring and support measures. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue STRENSIQ and immediately initiate appropriate medical treatment, including use of epinephrine. Inform patients of the symptoms of life-threatening hypersensitivity reactions, including anaphylaxis and to seek immediate medical care should symptoms occur *[see Warnings and Precautions (5.1)]*.

WARNINGS AND PRECAUTIONS

- **Life-threatening hypersensitivity reactions, including anaphylaxis,** have been reported in STRENSIQ-treated patients. Signs and symptoms consistent with anaphylaxis included difficulty breathing, choking sensation, nausea, periorbital edema, and dizziness. These reactions have occurred within minutes after subcutaneous administration of STRENSIQ and have been observed more than 1 year after treatment initiation. Other hypersensitivity reactions have also been reported in STRENSIQ-treated patients, including vomiting, fever, headache, flushing, irritability, chills, erythema, rash, pruritus, and oral hypoesthesia. Consider the risks and benefits of re-administering STRENSIQ following a severe reaction. If the decision is made to re-administer, monitor patients for a reoccurrence of signs and symptoms of a severe hypersensitivity reaction.

Please see additional Important Safety Information on the reverse and full Prescribing Information for STRENSIQ (asfotase alfa), including Boxed WARNING regarding hypersensitivity reactions including anaphylaxis.

The Alexion support service team is here to help you and your patients navigate this journey. Your Regional Account Manager is your main point of contact and will connect you directly with your assigned representatives from each of the groups below.

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ALEXION® AstraZeneca Rare Disease

Field Reimbursement Managers (FRMs):

The FRM team is available to help you navigate the landscape when it comes to getting STRENSIQ approved for your patients based on their individual insurance situation.

www.alexionaccessnavigator.com/strensiq

ONESOURCE® Personalized Patient Support from Alexion

OneSource™ is a free, personalized patient support program offered by Alexion. After enrolling in OneSource™, your patient will be matched with a dedicated OneSource™ Case Manager who can provide personalized support, including access to:

- Education on their disease and treatment
- Connections to other people impacted by HPP
- Information on copay support and financial assistance programs
- Treatment support

P: 888-765-4747
OneSource@Alexion.com
www.AlexionOneSource.com

PANTHERRARE

This specialty pharmacy dispenses STRENSIQ and provides:

- Help coordinating your patient's prescription
- Shipments and ongoing refills
- Instructions for self-administration
- 24/7 support

P: 844-787-6747 (ext 8008)
F: 844-787-2527
strensiqrph@pantherxrare.com
www.pantherxrare.com

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- **Lipodystrophy:** Localized lipodystrophy, including lipoatrophy and lipohypertrophy has been reported at injection sites after several months in patients treated with STRENSIQ in clinical trials. Advise patients to follow proper injection technique and to rotate injection sites.
- **Ectopic Calcifications:** Patients with HPP are at increased risk for developing ectopic calcifications. Events of ectopic calcification, including ophthalmic (conjunctival and corneal) and renal (nephrocalcinosis, nephrolithiasis), have been reported in the clinical trial experience with STRENSIQ. There was insufficient information to determine whether the reported events were consistent with the disease or due to STRENSIQ. No visual changes or changes in renal function were reported resulting from the occurrence of ectopic calcifications.

  Ophthalmology examinations and renal ultrasounds are recommended at baseline and periodically during treatment with STRENSIQ to monitor for signs and symptoms of ophthalmic and renal ectopic calcifications and for changes in vision or renal function.
- **Possible Immune-Mediated Clinical Effects:** In clinical trials, most STRENSIQ-treated patients developed anti-asfotase alfa antibodies and neutralizing antibodies which resulted in reduced systemic exposure of asfotase alfa. In postmarketing reports, some STRENSIQ-treated patients with initial therapeutic response subsequently developed recurrence and worsening in disease-associated laboratory and radiographic biomarkers (some in association with neutralizing antibodies) suggesting possible immune-mediated effects on STRENSIQ's pharmacologic action resulting in disease progression. The effect of anti-asfotase alfa antibody formation on the long-term efficacy of STRENSIQ is unknown. There are no marketed anti-asfotase alfa antibody tests. If patients experience progression of HPP symptoms or worsening of disease-associated laboratory and imaging biomarkers after a period of initial therapeutic response to STRENSIQ, consider obtaining anti-asfotase alfa antibody testing by contacting STRENSIQ Medical Information at Alexion at 1-888-765-4747 or by email at medinfo@alexion.com. Close clinical follow up is recommended.

ADVERSE REACTIONS

In clinical trials, the most common adverse reactions (≥ 10%) reported were injection site reactions (63%), lipodystrophy (28%), ectopic calcifications (14%), and hypersensitivity reactions (12%). Possible immune-mediated clinical effects have been identified during post-approval use of STRENSIQ.

DRUG INTERACTIONS

Drug Interference with Laboratory Tests:

- Laboratory tests utilizing alkaline phosphatase (ALP) as a detection reagent could result in erroneous test results for patients receiving treatment due to the presence of asfotase alfa in clinical laboratory samples. Inform laboratory personnel that the patient is being treated with STRENSIQ and discuss use of an alternative testing platform which does not utilize an ALP-conjugated test system.
- Elevated serum ALP measurements detected through clinical laboratory testing are expected in patients receiving STRENSIQ due to circulating concentrations of asfotase alfa. Do not rely on serum ALP measurements for clinical decision making in patients treated with STRENSIQ.

SPECIAL POPULATIONS

- **Pregnancy & Lactation:** There are no available data on STRENSIQ use in pregnant women, the presence of STRENSIQ in human milk, or the effects on the breastfed infant or on milk production, to inform a drug associated risk.

To report SUSPECTED ADVERSE REACTIONS, 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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