STRENSIQ® (asfotase alfa) Prescription (Rx) Form for the Treatment of Pediatric-Onset* Hypophosphatasia (HPP)

Phone: 1-844-787-6747 (ext 8008) **Fax:** 1-844-787-2527

Fax this form to PANTHERx Rare to document medical necessity for initiating treatment.
Note: Additional Information may be required based on insurance plan.

**Patients with perinatal/infantile- and juvenile-onset HPP*

Patient information

First name:_____ Last name:_____

Address:_____

City:_____ State:_____ ZIP code:_____

Date of birth:_____ Sex: ☐ Male ☐ Female

Email address:_____

Phone:_____

☐ Home ☐ Work ☐ Cell

☐ OK to leave message ☐ OK to text

Parent (guardian)/caregiver name(s) (if applicable):

_____

Primary diagnosis:

☐ ICD-10: E83.3 - Disorders of phosphorus metabolism and phosphatases

☐ ICD-10: E83.31 - Familial hypophosphatemia (perinatal/infantile- and juvenile-onset HPP)†

☐ ICD-10: E83.39 - Other disorders of phosphorus metabolism (perinatal/infantile- and juvenile-onset HPP)†

†*These ICD-10 diagnosis codes are not intended to be promotional or to encourage or suggest a use of drug that is inconsistent with FDA-approved use. The codes provided are not exhaustive and additional codes may apply. Descriptions in parentheses were added by Alexion for clarification and do not appear in these ICD-10 codes.*

Required labs and/or documentation:

☐ Alkaline phosphatase (ALP)

☐ Pyridoxal-5'-phosphate (PLP) or phosphoethanolamine (PEA)

☐ Perinatal/infantile-onset HPP signs and symptoms

☐ Juvenile-onset HPP signs and symptoms

☐ Current HPP signs and symptoms

Please attach copies of lab values if available.

Prescription for STRENSIQ

Patient's current weight: _____kg or _____lb

Date of weight: ____/____/____

STRENSIQ is a weight-based medication with two concentrations, 40 mg/1.0 mL and 80 mg/0.8 mL, which can be utilized independently or in combination depending on a patient's weight. **It is recommended to check both dosing concentration boxes below for patients weighing >40 kg to permit specialty pharmacy PANTHERx Rare to determine vial strengths and minimize waste.**

Dosing concentration

☐ 40 mg/1.0 mL

Dosing frequency

☐ 1 mg/kg, 6 times per week

☐ 2 mg/kg, 3 times per week

Other:_____

--- and/or ---

☐ 80 mg/0.8 mL
(is not recommended for use in pediatric patients <40 kg)

☐ 1 mg/kg, 6 times per week

☐ 2 mg/kg, 3 times per week

Other:_____

Dispense 28-day supply

Refill X 11 or

Other:_____

Pharmacy will dispense needles and syringes required for subcutaneous administration of STRENSIQ.

Prescriber information

First name:_____ Last name:_____

Professional designation:_____

Physician specialty:_____ NPI#:_____

Office contact name:_____

Office contact phone:_____

Office contact email:_____

Preferred method of contact: ☐ Phone ☐ Email

Clinic/hospital affiliation:_____

Address:_____

City:_____State:_____ ZIP code:_____

Phone:_____ Fax:_____

Healthcare and prescription drug insurance information

Please attach copies of both sides of patient's healthcare and prescription drug insurance card(s).

Primary insurance:_____

Member ID:_____

Group number:_____

Policy holder first name:_____

Policy holder last name:_____

Pharmacy Benefit Manager (PBM):_____

Rx BIN:_____

Rx PCN:_____

Rx Group:_____

Prescriber authorization

PLEASE NOTE: In New York, please attach copies of all prescriptions on official New York State prescription forms.
I authorize the Specialty Pharmacy as my designated agent and on behalf of my patient to forward the above statement of medical necessity and furnish any information on this form to the insurer of the above-named patient.

SIGNATURE STAMPS NOT ACCEPTABLE

_____ _____

Prescriber signature (dispense as written) Date

SIGNATURE STAMPS NOT ACCEPTABLE

_____ _____

Prescriber signature (substitution permitted) Date

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

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.
- **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

Please see full Prescribing Information for STRENSIQ (asfotase alfa), including Boxed WARNING regarding hypersensitivity reactions including anaphylaxis.

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AstraZeneca Rare Disease

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