Zelvysia™
(sapropterin dihydrochloride)
Powder for Oral Solution

ZELVYSIA™ (sapropterin dihydrochloride)
Powder for Oral Solution
Prescription Start Form

Phone: 773-598-6135
Fax: 877-299-8203
E-Prescribe to Orsini:
(NPI# 1073608998)

Patient Information *(Please Print)*

Last Name: First Name: SSN: Sex: M F

Address: City: State: Zip:

Primary Phone #: Alternate Phone #:

Date Of Birth:
mm/dd/year

If Patient is a Minor, Guardian/Parent Name: Relationship to Patient:

Insurance Information

Please attach front and back of patient's insurance card, prescription card, and/or Medicaid card

Primary Insurance: Phone #:

Policy Holder: Policy #: Group #:

Secondary Insurance: Phone #:

Policy Holder: Policy #: Group #:

Physician Information

Prescriber: Institution:

NPI:

Address: City: State: Zip:

Name & Title of Office Contact: Office Contact Email:

Office Contact Phone #: Office Contact Fax:

Prior Authorization Office Contact: Prior Authorization Office Contact #:

Clinical Information

Please fax clinical documentation to pharmacy along with Prescription Start Form

Please check applicable ICD-10 code:

- ○ E70.0 - Classical Phenylketonuria (PKU)

E70.1- Other Hyperphenylalaninemias *(please specify)*

- ○ Phenylketonuria
- ○ Tetrahydrobiopterin Deficiency (BH4)
- ○ Hyperphenylalaninemia
- ○ Maternal Phenylketonuria

○ Other

Allergies: ☐ No Known Drug Allergies

Concurrent Medications:

Baseline Blood Phe Levels
(before trial)

Date Phe Level Measured
(mm/dd/yyyy)

Continued on next page

Prescription Information

Current weight: ____ kg Dose per kg body weight: ◯ 10 mg/kg ◯ 20 mg/kg ◯ Other ____ mg/kg

Number of days' supply/prescription: ◯ 30 days ◯ 90 days ◯ One (1) Year and ____ Refill(s)

◯ ZELVYSIA™, **Powder 500 mg** / Number of packets per day: ____

◯ ZELVYSIA™, **Powder 100 mg** / Number of packets per day: ____

Patient Directions *(check all that apply)*:

◯ Please contact your physician before starting use of this medication.

◯ Take ____ **500 mg ZELVYSIA™** (Powder for Oral Solution) and ____ **100 mg ZELVYSIA™** (Powder for Oral Solution) once daily, as directed, with meal, for a total dose of ____ mg/day.

◯ Other ____

I certify I am prescribing ZELVYSIA™ (Powder for Oral Solution) for this patient for a medically necessary purpose.

Date Written: ____

Dispense as Written: _____ Substitution Allowed: _____

(Stamped Signatures Are Not Valid) *(Stamped Signatures Are Not Valid)*

Please see Important Safety information on page 3. For more information, please see full Prescribing Information, including Instructions for Use, or go to ZelvysiaHCP.com

Zelvysia™
(sapropterin dihydrochloride)
Powder for Oral Solution

INDICATION

ZELVYSIA™ (sapropterin dihydrochloride) is a phenylalanine hydroxylase activator indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients 1 month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). ZELVYSIA is to be used in conjunction with a Phe-restricted diet.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Hypersensitivity Reactions, Including Anaphylaxis:** Avoid use in patients with a history of anaphylaxis to sapropterin. Discontinue treatment if anaphylaxis occurs and initiate appropriate medical care. Continue dietary Phe restrictions.
- **Upper Gastrointestinal (GI) Mucosal Inflammation:** Serious GI adverse reactions (eg, esophagitis, gastritis, ulcer, bleeding) have been reported. Monitor for signs and symptoms.
- **Hypophenylalaninemia:** May occur; increased risk in children <7 years of age treated with doses of 20 mg/kg per day. Monitor closely.
- **Blood Phe Monitoring:** Frequent blood Phe monitoring is required to ensure levels remain in the desirable range. Prolonged high Phe can cause severe neurologic damage (eg, intellectual disability, developmental delay, microcephaly, delayed speech, seizures, behavioral abnormalities). Prolonged low Phe can lead to catabolism and adverse developmental outcomes. Active management of dietary protein and Phe restriction is required.
- **Lack of Biochemical Response:** Not all patients with PKU respond. Assess response through a therapeutic trial; response cannot be pre-determined by laboratory testing.
- **Interactions with Levodopa:** May cause seizures, exacerbation of seizures, overstimulation, or irritability. Monitor for changes in neurologic status.
- **Hyperactivity:** Monitor for signs of hyperactivity.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥4%) are headache, rhinorrhea, pharyngolaryngeal pain, diarrhea, vomiting, cough, and nasal congestion.

DRUG INTERACTIONS

- **Folate Synthesis Inhibitors (eg, methotrexate, valproic acid, phenobarbital, trimethoprim):** May decrease BH4 and increase Phe. Monitor Phe more frequently; adjust dosage as needed.
- **PDE-5 Inhibitors (eg, sildenafil, vardenafil, tadalafil):** Both ZELVYSIA and PDE-5 inhibitors may induce vasorelaxation and hypotension. Monitor blood pressure.

To report SUSPECTED ADVERSE REACTIONS, contact Aucta Pharmaceuticals, Inc. at 1-800-655-9902, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information, including Patient Information and Instructions for Use.

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