

PATIENT INFORMATION
ZELVYSIA (zel-VIS-ee-ah)
(sapropterin dihydrochloride)
powder for oral solution

What is Zelvysia?

Zelvysia is a prescription medicine used to lower blood levels of phenylalanine (Phe), in adults and children 1 month of age and older with a certain type of phenylketonuria (PKU). Zelvysia is used along with a Phe-restricted diet.

What should I tell my doctor before taking Zelvysia?

Before you take Zelvysia, tell your doctor about all your medical conditions, including if you:

- are allergic to sapropterin dihydrochloride or any of the ingredients in Zelvysia. See the list of ingredients in Zelvysia at the end of this leaflet
- have poor nutrition or loss of appetite
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed. It is not known if sapropterin dihydrochloride passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take Zelvysia

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal, and dietary supplements. Zelvysia and other medicines may interact with each other.

Especially tell your doctor if you take:

- a medicine that contains levodopa
- an antifolate medicine
- sildenafil (Revatio, Viagra), tadalafil (Adcirca, Cialis), vardenafil (Staxyn, Levitra)

Tell your doctor if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take Zelvysia?

- Take Zelvysia exactly as your doctor tells you. Your doctor should tell you how much Zelvysia to take and when to take it.
- Your doctor may change your dose of Zelvysia depending on how you respond to treatment.
- Take Zelvysia 1 time each day with a meal. It is best to take Zelvysia at the same time each day.
- Zelvysia comes as powder for oral solution.
 - Be sure that you know what dose of Zelvysia powder your doctor prescribed and whether you should use Zelvysia 100-mg packets, Zelvysia 500-mg packets, or both types of packets to prepare your dose.
 - Open Zelvysia powder packets only when you are ready to use them.
 - **Zelvysia powder for oral solution should be dissolved in water or apple juice.** You may also mix the powder for oral solution in a small amount of soft food, such as apple sauce or pudding, before taking. See the detailed "Instructions for Use" that comes with Zelvysia for information about the correct way to dissolve and take a dose of Zelvysia powder for oral solution.
- It is not possible to know if Zelvysia will work for you until you start taking Zelvysia. Your doctor will check your blood Phe levels when you start taking Zelvysia to see if the medicine is working.
- During treatment with Zelvysia:
 - Any change you make to your diet may affect your blood Phe level. Follow your doctor's instructions carefully and do not make any changes to your dietary Phe intake without first talking with your doctor. Even if you take Zelvysia, if your Phe blood levels are not well controlled, you can develop severe neurologic problems.
 - Your doctor should continue to monitor your blood Phe levels often during your treatment with Zelvysia **to make sure that your blood Phe levels are not too high or too low.**
 - If you have a fever, or if you are sick, your blood Phe level may go up. Tell your doctor as soon as possible so they can change your dose of Zelvysia to help keep your blood Phe levels in the desired range.
- If you forget to take your dose of Zelvysia, take it as soon as you remember that day. Do not take 2 doses in a day.
- If you take too much Zelvysia, call your doctor for advice.

What are the possible side effects of Zelvysia?

Zelvysia can cause serious side effects, including:

- **Severe allergic reactions.** Stop taking Zelvysia and get medical help right away if you develop any of these symptoms of a severe allergic reaction:
 - wheezing or trouble breathing
 - coughing
 - feeling lightheaded or you faint
 - flushing
 - nausea
 - rash
- **Inflammation of the lining of the stomach (gastritis) or esophagus (esophagitis).** Gastritis or esophagitis can happen with Zelvysia and may be severe. **Call your doctor right away if you have any of these signs or symptoms:**
 - severe upper stomach-area (abdominal) discomfort or pain, nausea, and vomiting
 - blood in your vomit or stool
 - black, tarry stools
 - difficulty swallowing
 - loss of appetite
 - pain in the throat
- **Phe levels that are too low.** Some children under 7 years of age who take high doses of Zelvysia each day may experience low Phe levels.
- **Too much or constant activity (hyperactivity) can happen with Zelvysia.** Tell your doctor if you have any signs of hyperactivity, including:
 - fidgeting or moving around too much
 - talking too much

The most common side effects of Zelvysia are:

- headache
- runny nose and nasal congestion
- sore throat
- diarrhea
- vomiting
- cough

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Zelvysia. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Zelvysia?

- Store Zelvysia at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect from moisture.

Keep Zelvysia and all medicines out of the reach of children.

General information about the safe and effective use of Zelvysia.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Zelvysia for a condition for which it was not prescribed. Do not give Zelvysia to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or doctor for information about Zelvysia that is written for health professionals.

What are the ingredients in Zelvysia?

Active ingredient: sapropterin dihydrochloride.

Zelvysia powder for oral solution inactive ingredients: ascorbic acid, mannitol, and potassium citrate.

Manufactured for:

Aucta Pharmaceuticals, Inc.
Piscataway, NJ 08854

For more information, go to [www. Zelvysia.com](http://www.Zelvysia.com) or call 1-800-655-9902.