

## Instructions for Use

### **Zelvysia (zel-VIS-ee-ah) (sapropterin dihydrochloride) powder for oral solution**

Read this Instructions for Use before you start taking Zelvysia and each time you refill your prescription. There may be new information. This information does not take the place of talking with your healthcare provider about your treatment. Talk to your doctor if you have any questions about the right dose of Zelvysia to take or how to mix it.

#### **Important information:**

- Zelvysia comes as in a packet containing powder.
- 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, or based on your baby's weight. If your baby weighs 22 pounds or less, follow the section called "**Instructions for giving Zelvysia powder for oral solution (Zelvysia 100 mg packets) to babies who weigh 22 pounds or less**".
- Take Zelvysia 1 time each day with a meal. It is best to take Zelvysia at the same time each day.

#### **Instructions for taking Zelvysia powder for oral solution:**

For babies who weigh 22 pounds or less, see the section below called "**Instructions for giving Zelvysia powder for oral solution (Zelvysia 100 mg packets) to babies who weigh 22 pounds or less.**"

Zelvysia powder for oral solution should be dissolved in water or apple juice. The powder for oral solution may also be mixed in a small amount of soft foods, such as apple sauce or pudding.

#### **To dissolve Zelvysia powder for oral solution:**

- Be sure that you know what dose of Zelvysia your doctor has prescribed and whether you should use Zelvysia 100-mg packets, Zelvysia 500-mg packets, or both types of packets to prepare your dose.
- Open the packet(s) of Zelvysia powder for oral solution by folding and tearing, or cutting at the dotted line in the upper right corner of the packet. Open the packet(s) only when you are ready to use them.
- Empty the contents of the packet(s) into 4 ounces to 8 ounces (1/2 cup to 1 cup) of water or apple juice.
- Drink within 30 minutes.

#### **Instructions for giving Zelvysia powder for oral solution (Zelvysia 100 mg packets) to babies who weigh 22 pounds or less:**

- The dose of Zelvysia is based on body weight. This will change as your baby grows. Your doctor will tell you:
  - the number of Zelvysia 100-mg packets needed for 1 dose
  - the amount of water or apple juice needed to mix 1 dose of Zelvysia
  - the amount of the mixture (powder and water or apple juice) you will need to give your baby his or her prescribed dose of medicine.

- Give your baby the prescribed amount of mixture (powder and water or apple juice) within 30 minutes after mixing. If you are not able to give your baby's dose within 30 minutes after mixing, pour the unused medicine into the trash. You will need to mix a new dose.

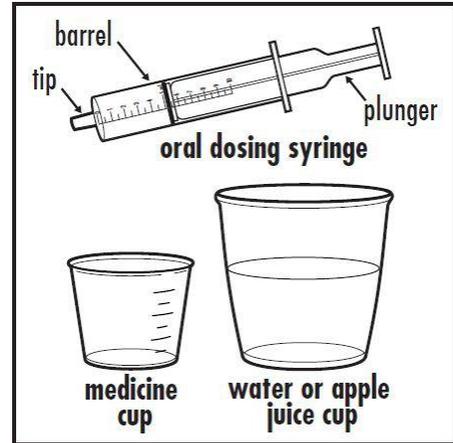
**Supplies needed to mix and give your baby's dose of Zelvysia powder for oral solution:**

- the number of Zelvysia 100-mg packets needed for 1 dose
- a small cup of water or apple juice
- one 30 mL medicine cup for mixing
- small spoon or clean utensil for mixing
- 10-mL oral dosing syringe
- scissors (optional)

Ask your pharmacist for a 30-mL medicine cup for mixing and an oral dosing syringe if you do not have these supplies.

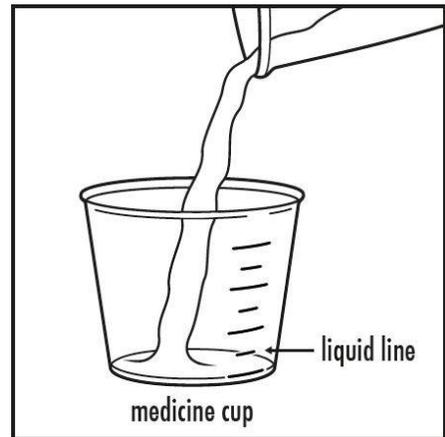
**Step 1:** Find a clean, flat work surface.

**Step 2:** Place a small cup of water or apple juice, the oral dosing syringe, and an empty medicine cup on your clean, flat work surface (see Figure A).



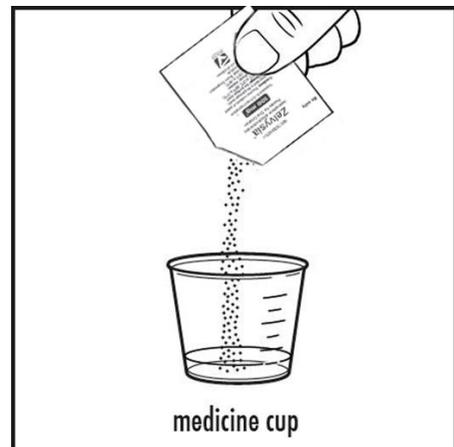
**Figure A**

**Step 3:** Pour 5 mL or 10 mL of water or apple juice from the small cup into the medicine cup, as instructed by your doctor. Check to make sure that the amount of liquid lines up with the amount that your doctor tells you (see Figure B).



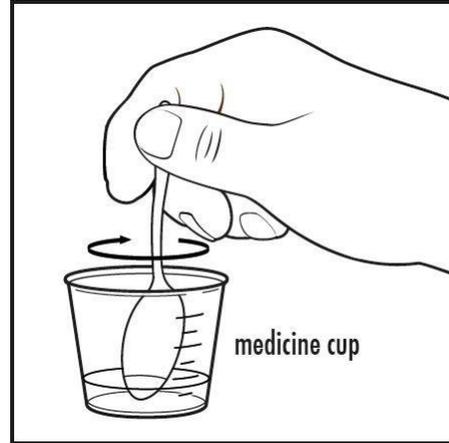
**Figure B**

**Step 4:** Check the label on the Zelvysia packet(s). If the packet is marked Zelvysia 100 mg, empty the entire contents of the Zelvysia packet into the medicine cup (see Figure C).



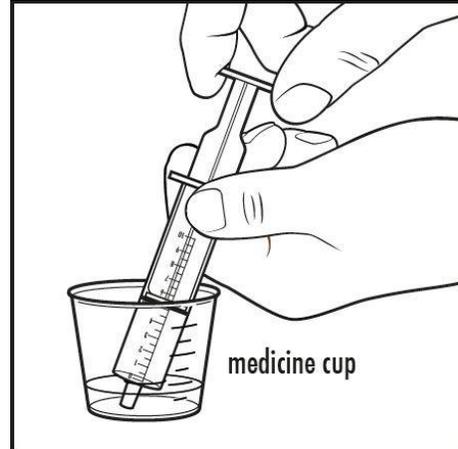
**Figure C**

**Step 5:** Stir the mixture with the small spoon or other clean utensil until all of the powder completely dissolves (see Figure D).



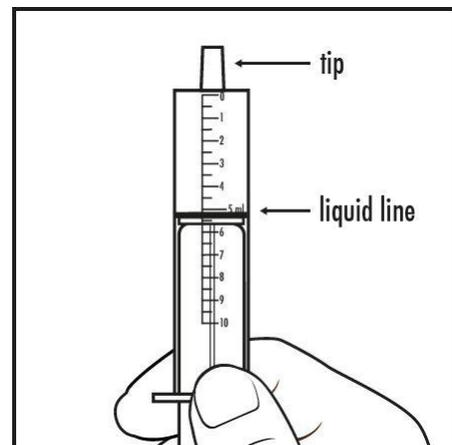
**Figure D**

**Step 6:** To give a dose of Zelvysia to your baby: Place the tip of the oral dosing syringe into the liquid inside the medicine cup. Pull back on the plunger and draw up the amount of the mixture prescribed by your doctor (see Figure E).



**Figure E**

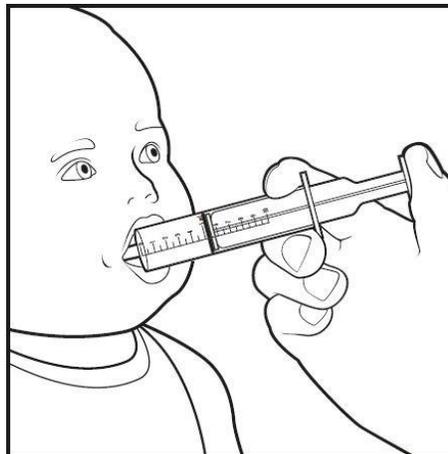
**Step 7:** Take the oral dosing syringe out of the medicine cup. Carefully turn the oral dosing syringe so that the tip is pointing up. Check to make sure that the amount of medicine in the oral dosing syringe lines up with the amount of mixture prescribed by your doctor (see Figure F).



**Figure F**

**Step 8:** Place the tip of the oral dosing syringe into your baby's mouth. Point the tip of the oral dosing syringe toward either cheek (see Figure G).

Push on the plunger slowly, a small amount at a time, until all of the mixture in the oral dosing syringe is given.



**Figure G**

**Step 9:** Throw away any remaining mixture. Remove the plunger from the barrel of the oral dosing syringe. Wash the oral dosing syringe and medicine cup with warm water and air dry. When the oral dosing syringe is dry, put the plunger back into the barrel. Store the oral dosing syringe and medicine cup for the next use.

### **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.**

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

**Aucta Pharmaceuticals, Inc.**  
Piscataway, NJ 08854

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