

## INSTRUCTIONS FOR USE

### Carglumic Acid Tablets for Oral Suspension

#### **Important information:**

- **Carglumic Acid tablets for oral suspension must be mixed in water before taking.** Carglumic Acid tablets for oral suspension should not be mixed in any other food or liquid.
- **Do not** swallow Carglumic Acid tablets for oral suspension whole.
- **Do not** crush Carglumic Acid tablets for oral suspension.
- Take Carglumic Acid tablets for oral suspension **right before** meals or feedings.
- The Carglumic Acid tablet for oral suspension and water mixture has a slightly sour taste.

You may need to ask your healthcare provider or pharmacist for a medicine cup to measure the correct amount of water you will need to prepare the dose of Carglumic Acid tablets for oral suspension.

**The Carglumic Acid tablet for oral suspension tablet has 3 lines used for splitting the tablet into 4 equal parts in order to get the prescribed dose.** Ask your healthcare provider if you have any questions about how to split the tablet the right way or have any questions about the prescribed dose.

#### **Taking Carglumic Acid tablets for oral suspension by mouth using a cup:**

##### **Children and Adults**

1. Add a minimum of 2.5 mL of water into a small cup for each Carglumic Acid tablet for oral suspension, or each  $\frac{1}{2}$  or  $\frac{1}{4}$  Carglumic Acid tablet for oral suspension, needed for the prescribed dose. For example:
  - If the prescribed dose is 2 Carglumic Acid tablets for oral suspension, add a minimum of 5 mL of water into the cup.
  - If the prescribed dose is 2 and a  $\frac{1}{4}$  Carglumic Acid tablets for oral suspension, add a minimum of 7.5 mL of water into the cup.
  - If the prescribed dose is 2 and a  $\frac{1}{2}$  Carglumic Acid tablets for oral suspension, add a minimum of 7.5 mL of water into the cup.
  - Ask your healthcare provider if you are not sure of how much water you should use for the prescribed dose of Carglumic Acid tablets for oral suspension.
2. Place the prescribed number of Carglumic Acid tablets for oral suspension into the water in the cup.
3. Carefully stir the Carglumic Acid tablet for oral suspension and water mixture in the cup to avoid spilling the mixture. Carglumic Acid tablets for oral suspension do not dissolve completely in water.
4. Swallow the Carglumic Acid tablets for oral suspension and water mixture **right away**.
5. Pieces of the tablet may remain in the cup. Add more water to the cup to rinse the cup and swallow the mixture **right away**.
6. Repeat step 5 until there are no pieces of the tablet left in the cup.

#### **Taking Carglumic Acid tablets for oral suspension by mouth using an oral syringe:**

##### **Children**

1. Add a minimum of 2.5 mL of water into a small cup for each Carglumic Acid tablet for oral suspension, or each  $\frac{1}{2}$  or  $\frac{1}{4}$  Carglumic Acid tablet for oral suspension, needed for the prescribed dose. For example:
  - If the prescribed dose is 2 Carglumic Acid tablets for oral suspension, add a minimum of 5 mL of water into the cup.
  - If the prescribed dose is 2 and a  $\frac{1}{4}$  Carglumic Acid tablets for oral suspension, add a minimum of 7.5 mL of water into the cup.
  - If the prescribed dose is 2 and a  $\frac{1}{2}$  Carglumic Acid tablets for oral suspension, add a minimum of 7.5 mL of water into the cup.
  - Ask your healthcare provider if you are not sure of how much water you should use for the prescribed dose of Carglumic Acid tablets for oral suspension.
2. Place the prescribed number of Carglumic Acid tablets for oral suspension into the water in the cup.
3. Carefully stir the Carglumic Acid tablets for oral suspension and water mixture in the cup to avoid spilling the mixture. Carglumic Acid tablets for oral suspension do not dissolve completely in water.
4. Draw up all of the Carglumic Acid tablets for oral suspension and water mixture in the cup into an oral syringe.
5. Give your child the Carglumic Acid tablets for oral suspension and water mixture **right away** by placing the tip of the oral syringe along the inner cheek of their mouth, on either the right or left side. Slowly push all the way down on the plunger to give the medicine.
6. Pieces of the tablet may remain in the oral syringe. Refill the oral syringe with a minimum of 1 mL to 2 mL of water, and give your child the mixture **right away**.
7. Repeat step 6 until there are no pieces of the tablet left in the oral syringe.

**Giving Carglumic Acid tablets for oral suspension through a nasogastric (NG) or gastrostomy tube (G-tube):**

**Children and Adults**

1. Add a minimum of 2.5 mL of water into a small cup for each Carglumic Acid tablet for oral suspension, or each  $\frac{1}{2}$  or  $\frac{1}{4}$  Carglumic Acid tablet for oral suspension, needed for the prescribed dose. For example:
  - If the prescribed dose is 2 Carglumic Acid tablets for oral suspension, add a minimum of 5 mL of water into the cup.
  - If the prescribed dose is 2 and a  $\frac{1}{4}$  Carglumic Acid tablets for oral suspension, add a minimum of 7.5 mL of water into the cup.
  - If the prescribed dose is 2 and a  $\frac{1}{2}$  Carglumic Acid tablets for oral suspension, add a minimum of 7.5 mL of water into the cup.
  - Ask your healthcare provider if you are not sure of how much water you should use for the prescribed dose of Carglumic Acid tablets for oral suspension.
2. Place the prescribed number of Carglumic Acid tablets for oral suspension into the water in the cup.
3. Carefully stir the Carglumic Acid tablets for oral suspension and water mixture in the cup to avoid spilling the mixture. Carglumic Acid tablets for oral suspension do not dissolve completely in water.
4. Draw up all of the Carglumic Acid tablets for oral suspension and water mixture in the cup into a catheter-tip syringe.

5. Connect the catheter-tip syringe to the NG tube or G-tube.
6. Give the Carglumic Acid tablet for oral suspension and water mixture through the NG tube or G-tube **right away**.
7. Pieces of the tablet may remain in the catheter-tip syringe or NG tube or G-tube.
8. Refill the catheter-tip syringe with 1 mL to 2 mL of water and flush the NG tube or G-tube **right away**.
9. Repeat step 8 until there are no pieces of the tablet left in the catheter-tip syringe or NG tube or G-tube.

#### **How should I store Carglumic Acid tablets for oral suspension?**

- **Before opening**, store Carglumic Acid tablets for oral suspension at 20° to 25°C (68° to 77°F) in the container it comes in.
- **After opening**, store Carglumic Acid tablets for oral suspension at room temperature between 20° to 25°C (68° to 77°F). **Do not** store Carglumic Acid tablets for oral suspension in a refrigerator after opening.
  - Keep Carglumic Acid tablets for oral suspension in a tightly closed container to protect the tablets from moisture.
  - Write the date the Carglumic Acid tablets for oral suspension container is opened on the container label. Throw away any unused tablets one month after opening the tablet container.
- Do not use Carglumic Acid tablets for oral suspension after the expiration date on the tablet container.
- **Keep Carglumic Acid tablets for oral suspension and all medicines out of the reach of children.**

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

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