

**INSTRUCTIONS FOR USE
MODEYSO [moh-DAY-soh]
(dordaviprone)
capsules, for oral use**

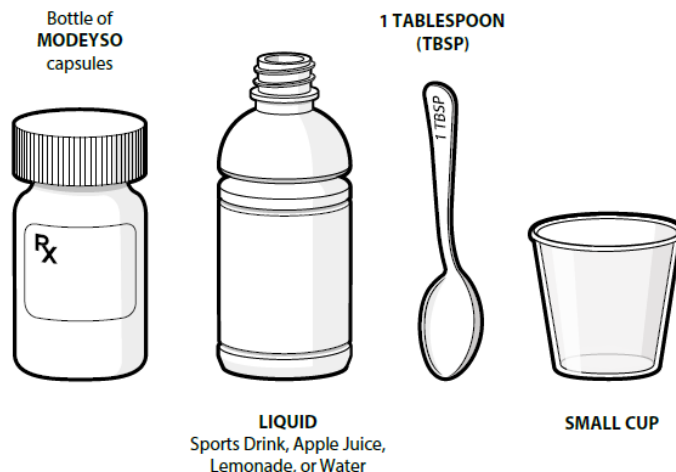
This Instructions for Use contains information on how to prepare and take or give MODEYSO capsules as a liquid.

Read this Instructions for Use carefully before you prepare and take or give a dose of MODEYSO for the first time and each time you or your child gets a prescription refill. There may be new information. This information does not take the place of talking with your healthcare provider about your or your child's medical condition or treatment.

Important Information You Need to Know Before Preparing and Taking or Giving MODEYSO Capsules as a Liquid.

- For oral use only (take by mouth).
- Take or give MODEYSO exactly as your healthcare provider tells you. Do not change the dose or stop taking MODEYSO without talking to your healthcare provider.
- Take or give MODEYSO 1 time each week on the same day of the week. Take or give all of the capsules prescribed for your dose at the same time.
- Take or give MODEYSO on an empty stomach, at least 1 hour before or 3 hours after eating food.
- If you or your child cannot swallow the capsules whole, the capsules can be dissolved in sports drink, apple juice, lemonade, or water and taken as a liquid.
- Check the expiration date on the MODEYSO bottle. Do not take or give MODEYSO if the expiration date has passed. Contact your pharmacist if the medicine is expired.
- Do not take or give MODEYSO if the bottle or the capsules are broken or damaged. Contact your healthcare provider or pharmacist for a replacement.

Supplies needed to prepare and dissolve MODEYSO capsules to take or give as a liquid.



Section A: Preparing and dissolving MODEYSO capsules to take or give as a liquid

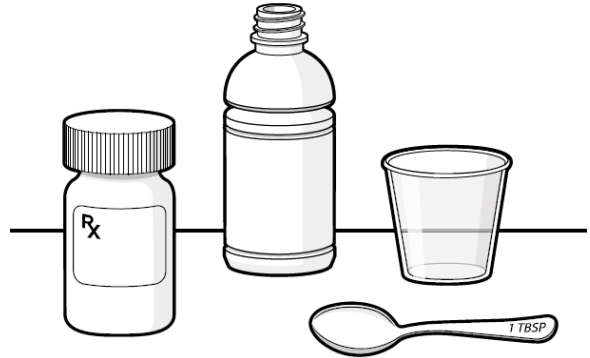
Preparing to dissolve the capsules

Step 1:

Wash and dry your hands.

Place the MODEYSO bottle on a clean, flat surface.

Gather the rest of the supplies you will need so they are ready to use.



Step 2:

Check the prescribed dose. Count out the number of MODEYSO capsules needed for the dose.



Opening the capsules

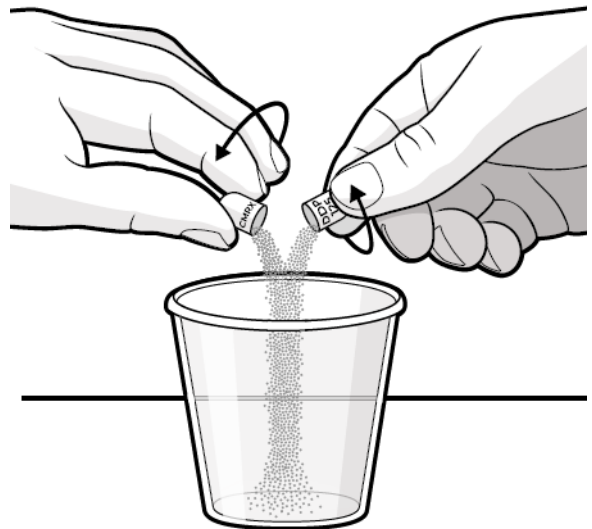
Step 3:

Hold the capsule over a clean, empty cup.

Carefully open the capsule by gently pulling and twisting both ends.

Slowly empty the contents (powder) into the cup.

If any powder remains inside the capsule shell, gently tap the shell over the cup to remove any remaining powder.



Step 4:

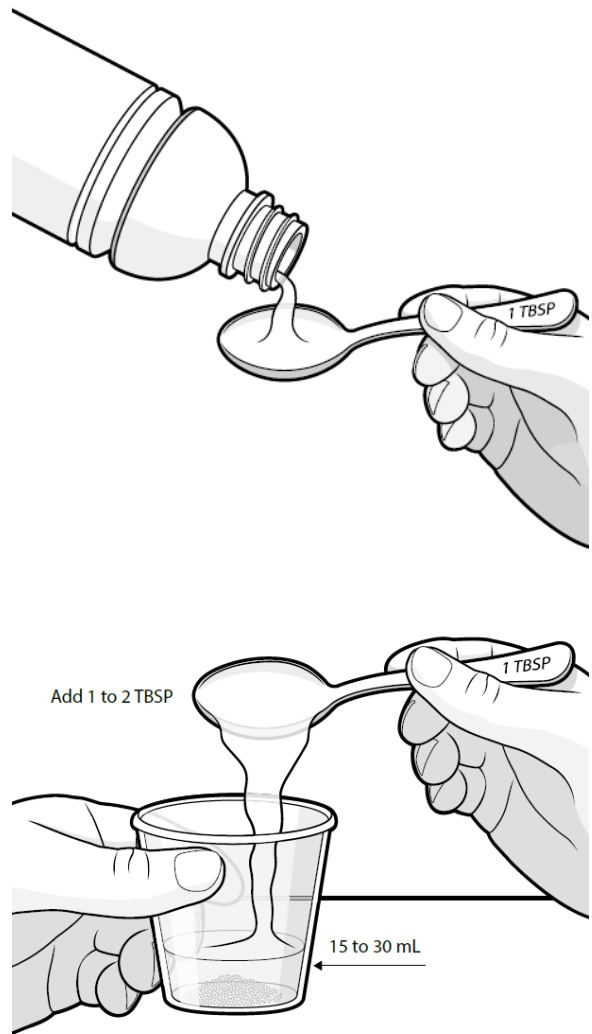
Repeat **Step 3** for each additional capsule needed for the prescribed dose.

Dissolving the capsules in liquid

Step 5:

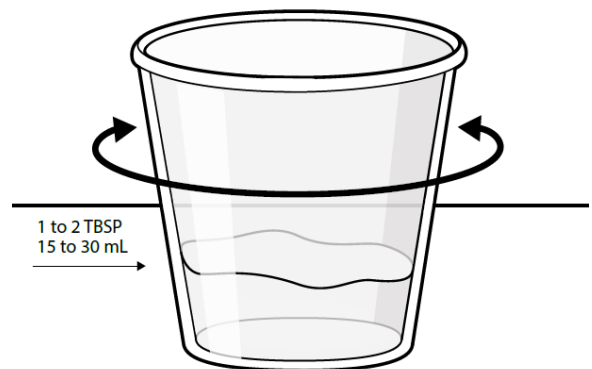
Use a tablespoon (15 mL) to measure the liquid.

Add **1 to 2** tablespoons (about 15 mL to 30 mL) of your chosen liquid (sports drink, apple juice, lemonade, or water) to the cup.



Step 6:

Gently swirl the liquid around the cup before taking or giving the mixture until no large chunks of powder remain. The mixture may look cloudy. This is normal and okay.



Section B: Taking or giving a dose of MODEYSO as a liquid

Step 7:

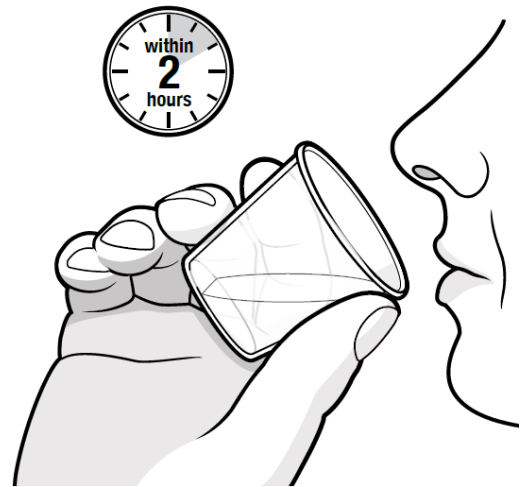
Take or give all of the mixture as soon as possible. Always take or give the mixture within 2 hours of preparing it.

An oral dosing syringe may be used to take or give the mixture by mouth. Refer to Section D for detailed instructions.

The mixture may be taken or given through a feeding tube. Refer to Section E for detailed instructions.

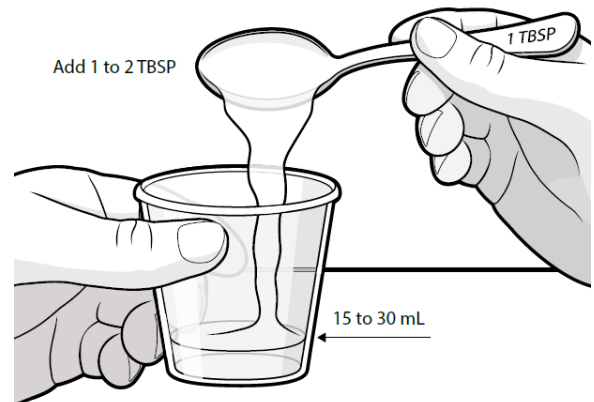
Throw away the mixture if it is not taken within 2 hours of preparing it and go back to Section A to prepare a new dose.

If vomiting happens after taking or giving the dose, or not all of the liquid is swallowed, **do not** take or give another dose. Take the next dose of MODEYSO on the next regularly scheduled day of the week.



Step 8:

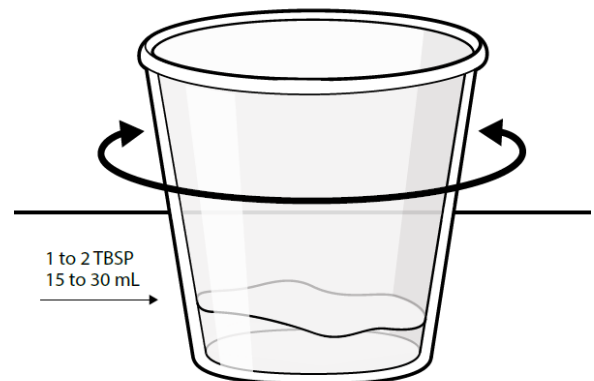
After taking or giving the dose, add **1 to 2** more tablespoons (about 15 mL to 30 mL) of your chosen liquid to the cup.





Step 9:

Swirl the liquid around the cup to make sure any remaining medicine is mixed with the liquid.

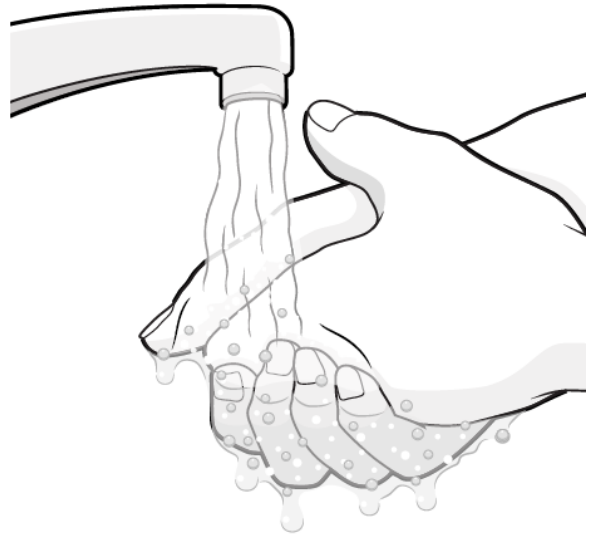
This helps make sure that no medicine is left behind.



<p>Step 10: Repeat Step 7.</p>	
<p>Section C: Disposing of (throwing away) empty MODEYSO capsule shells and cleaning the cup</p>	
<p>Step 11: After taking or giving the dose, throw empty capsule shells in the trash. Do not save or reuse empty capsules.</p>	 <p>A line drawing showing a right hand held palm down, dropping three empty capsule shells into a cylindrical trash can. The shells are small, oval-shaped, and have some markings on them. The trash can is shown from a top-down perspective.</p>
<p>Step 12: After taking or giving the dose, rinse the cup with warm running water to remove all remaining medicine.</p>	 <p>A line drawing showing a right hand holding a small, clear plastic cup under a running faucet. Water is flowing from the faucet into the cup. The hand is positioned to hold the cup steady while it is being rinsed.</p>

Step 13:

Wash your hands with soap and water.

**Section D: Taking or giving a dose of MODEYSO as a liquid using an oral dosing syringe**

If you are using an oral dosing syringe to take or give MODEYSO by mouth:

1. Follow **Steps 1 through 6 in Section A** to prepare the MODEYSO liquid mixture in a cup.
2. If there is a cap, remove the cap of the oral dosing syringe.
3. Push the plunger down into the oral dosing syringe as far as it will go.
4. Place the oral dosing syringe tip in the mixture in the cup. Pull up on the plunger to draw all the mixture into the oral dosing syringe.
5. You or your child should sit upright to take or give a dose of MODEYSO. Place the tip of the oral dosing syringe towards the inside of the cheek in your or your child's mouth.
6. Slowly push the medicine into the mouth by pressing down on the plunger, allowing time for swallowing. Do not forcefully push the plunger. This may cause choking.
7. You or your child may drink other liquids right away after swallowing the mixture.
8. **Steps 3 through 7 in this section** may be repeated until all the mixture has been taken or given.
9. After taking or giving the dose, add 1 to 2 more tablespoons (about 15 mL to 30 mL) of your chosen liquid to the cup.
10. Swirl the liquid around the cup to make sure any remaining medicine is mixed with the liquid. This helps make sure that no medicine is left behind.
11. Using the oral dosing syringe, repeat **Steps 3 through 6 in this section** until all of the mixture in the cup has been taken or given.
12. After completing **Step 11 in this section**, remove the plunger from the oral dosing syringe and rinse each part with warm running water to remove all remaining medicine. Allow the parts to air dry completely before putting the syringe back together.

Refer to **Section C: Disposing of (throwing away) empty MODEYSO capsule shells and cleaning the cup.**

Section E: Taking or giving a dose of MODEYSO as a liquid using a feeding tube

MODEYSO may be given through a naso-gastric (“ng”) or gastrostomy (“g”) feeding tube, as directed by your healthcare provider.

1. Follow **Steps 1 through 6 in Section A** to prepare the MODEYSO liquid mixture in a cup.
2. Flush the feeding tube according to the manufacturer's instructions before each dose.
3. Draw up the mixture into a catheter tip syringe.
4. Connect the syringe containing the mixture to the feeding tube.
5. Apply slow, steady pressure to the plunger to give all the contents of the syringe through the feeding tube.
6. After giving the dose, add 1 to 2 more tablespoons (about 15 mL to 30 mL) of your chosen liquid to the cup.
7. Swirl the liquid around the cup to make sure any remaining medicine is mixed with the liquid. This helps make sure that no medicine is left behind.
8. Using the syringe, repeat **Steps 3 through 5 in this section** until all the mixture in the cup has been given.
9. After completing **Step 8 in this section**, flush the feeding tube according to the manufacturer's instructions.
10. After completing **Step 9 in this section**, remove the plunger from the syringe and rinse each part with warm running water to remove all remaining medicine. Allow the parts to air dry completely before putting the syringe back together.

Refer to **Section C: Disposing of (throwing away) empty MODEYSO capsule shells and cleaning the cup.**

Storing MODEYSO

- Store MODEYSO at room temperature between 68°F to 77°F (20°C to 25°C).
- The MODEYSO bottle has a child-resistant closure.

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

Distributed by:

Jazz Pharmaceuticals, Inc.

Palo Alto, CA 94306

For more information, contact Chimerix, Inc. at 1-866-662-2679.

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

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