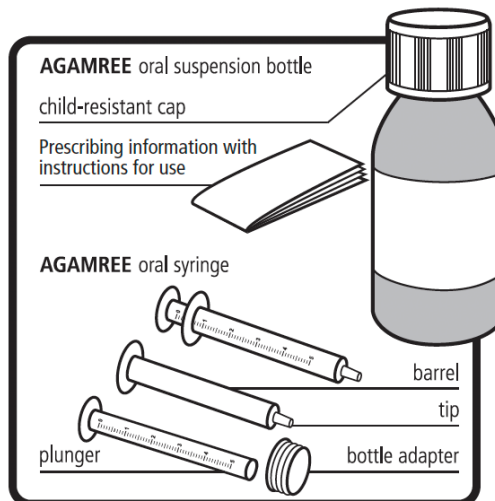


Instructions for Use
AGAMREE® (ah gam' ree)
(vamorolone)
40 mg/mL oral suspension

Read this Instructions for Use before you start using AGAMREE oral suspension and each time you get a new bottle. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

Supplies provided in the AGAMREE carton:

- 1 bottle containing 100 mL of AGAMREE, with a child-resistant cap
- 1 bottle adapter
- Two 5 mL oral syringes
- 1 Prescribing information with Instructions for Use




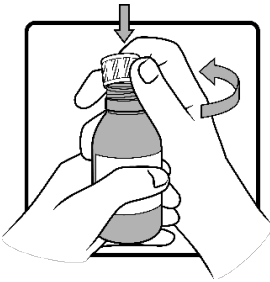
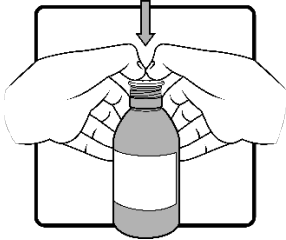
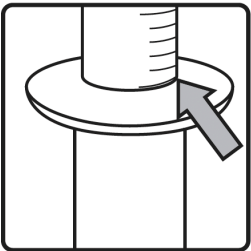
Important information you need to know before taking AGAMREE:

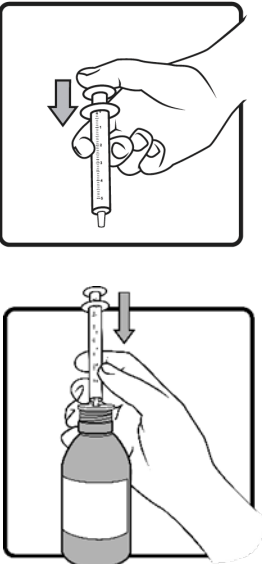
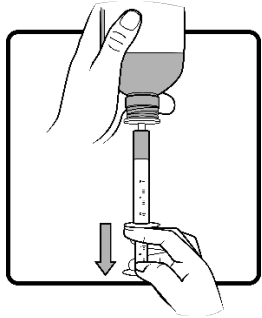
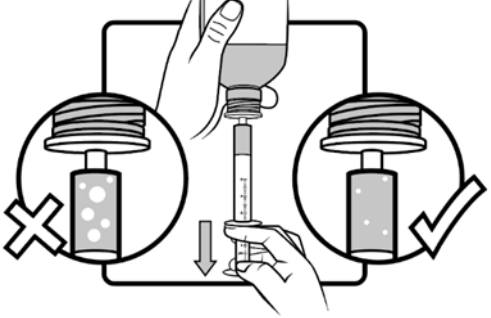

- **For oral use only** (take by mouth).
- **Always use the oral syringes provided with your AGAMREE oral suspension to make sure you measure the right amount.**
- Ask your healthcare provider or pharmacist to show you how to measure your prescribed daily dose using the oral syringe.
- Call your pharmacist if your oral syringes are lost or damaged.
- Each oral syringe can be used for 45 days. Call your pharmacist if you need more oral syringes.
- Take AGAMREE exactly as your healthcare provider tells you to take it. **Do not** stop taking AGAMREE suddenly without first speaking with your healthcare provider.
- AGAMREE oral suspension should be taken 1-time daily with a meal.
- **Do not** mix the AGAMREE oral suspension with any type of liquids before taking or giving the prescribed daily dose.
- **Do not** use AGAMREE 3 months after opening the bottle. Write the date of first opening on your AGAMREE bottle when you first open it.

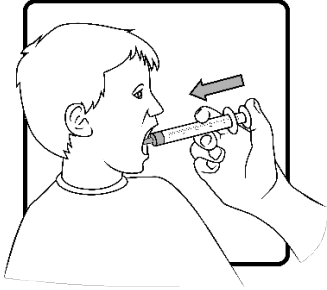

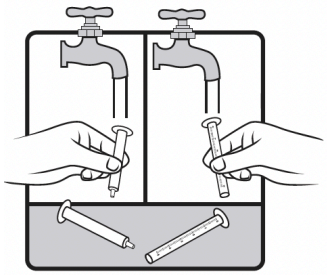
Storing AGAMREE

- Store the unopened bottle upright at room temperature between 68°F to 77°F (20°C to 25°C) in the original carton. After opening the bottle, store the bottle upright in a refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze.
- Throw away (discard) any unused AGAMREE oral suspension remaining after 3 months of first opening the bottle.

Keep AGAMREE oral suspension and all medicines out of the reach of children.

Preparing the AGAMREE bottle		
Step 1	<p>Place the child-resistant bottle cap on the bottle.</p> <p>Make sure the child-resistant bottle cap is tightly secured and shake the bottle well for about 30 seconds.</p>	
Step 2	<p>Open the bottle by firmly pressing down on the child-resistant bottle cap and turning it to the left (counter-clockwise).</p> <p>Do not throw away the child-resistant bottle cap.</p>	
Step 3	<p>Place the open bottle on a flat surface.</p> <p>Firmly insert the bottle adapter into the bottle by pushing it tightly into the top of the bottle.</p> <p>The top edge of the bottle adapter should be even with the bottle top.</p> <p>Do not remove the bottle adapter after it is inserted into the bottle.</p> <p>Write the date of first opening on your AGAMREE bottle when you first open it.</p>	
Preparing and withdrawing the AGAMREE dose		
Step 4	<p>Check your dose in milliliters (mL) as prescribed by your healthcare provider. Each mark on the oral syringe is equal to 0.1 mL.</p> <p>Do not take more than the prescribed daily dose.</p>	

<p>Step 5</p>	<p>Place the bottle on a flat surface.</p> <p>Before inserting the tip of the oral syringe into the bottle adapter, push the plunger completely down toward the tip of the oral syringe. Use 1 hand to hold the bottle upright. Insert the oral syringe tip firmly into the opening of the bottle adapter.</p>	
<p>Step 6</p>	<p>Hold the oral syringe in place and carefully turn the bottle upside down.</p> <p>Pull the plunger down slowly until you reach the mL markings on the plunger for the prescribed dose. Do not pull the plunger out of the oral dispenser.</p>	
<p>Step 7</p>	<p>If there are large bubbles in the oral syringe or if you draw up the wrong dose of AGAMREE, push the plunger all the way up so that AGAMREE flows back into the bottle. Pull the plunger down slowly until you reach the mL markings for your prescribed dose. Repeat Step 7 if any large air bubbles remain or if you draw up the wrong dose of AGAMREE.</p>	
<p>Step 8</p>	<p>Leave the tip of the oral syringe in the bottle and turn the entire bottle to an upright position. Slowly remove the oral syringe tip from the bottle by pulling the oral syringe straight up.</p> <p>Do not hold the oral syringe by the plunger, because the plunger may come out.</p> <p>Take or give AGAMREE right away after it is drawn up into the oral syringe.</p> <p>Do not store the filled oral syringe.</p>	

Taking AGAMREE	
Step 9	<p>The child or adult should sit upright to take a dose of AGAMREE.</p> <p>Place the oral syringe tip in the mouth towards the cheek and slowly push the plunger down until the oral syringe is empty.</p> <p>Do not forcefully push on the plunger. Do not give AGAMREE too fast into the back of the mouth or throat. This may cause choking.</p>
	
Step 10	If your prescribed dose is greater than 5 mL, repeat Steps 4 to 9 .
After taking or giving AGAMREE	
Step 11	<p>Put the child-resistant bottle cap back on the bottle and turn the cap to the right (clockwise) to close the bottle. Keep the bottle tightly closed after each use.</p>
	
Cleaning the oral syringes	
Step 12	<p>Remove the plunger from the barrel of the oral syringe.</p> <p>Rinse the barrel and plunger with running warm water only and let them air dry on a paper towel.</p> <p>When the oral syringe and plunger are dry, put the plunger back in the oral syringe for the next dose. Store the oral syringe in a clean, dry place.</p>
	

For further information call 1-833-422-8259 or go to www.YourCatalystPathways.com.
 Manufactured for: Catalyst Pharmaceuticals, Inc., Coral Gables, FL 33134
 This Instructions for Use has been approved by the U.S. Food and Drug Administration.
 Approved: 10/2023