



## Preparing and Administering AGAMREE®

### Illustrated Guide

Refer to the full 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.**



**Scan to download the  
full Instructions for Use**

#### **What is AGAMREE?**

AGAMREE is a prescription medicine used to treat Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.

#### **IMPORTANT SAFETY INFORMATION**

**Patients should not take AGAMREE** if they are allergic to vamorolone or any of the inactive ingredients in AGAMREE.

Please see Important Safety Information throughout and accompanying full Prescribing Information in pocket.

## Before You Administer AGAMREE®

### Important information you need to know before taking AGAMREE:

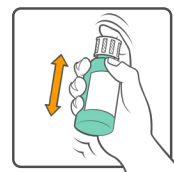
- **For oral use only** (take by mouth).
- **Always use the oral syringes provided with your AGAMREE oral suspension to make sure you measure the right amount.**
- Ask your healthcare provider or pharmacist to show you how to measure your prescribed daily dose using the oral syringe.
- Call your pharmacist 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. You will receive two 5-mL oral syringes with each shipment of AGAMREE.
- 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



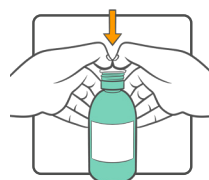
### Step 1

- Place the child-resistant bottle cap on the bottle.
- Make sure the child-resistant bottle cap is tightly secured and shake the bottle well for about 30 seconds.



### Step 2

- Open the bottle by firmly pressing down on the child-resistant bottle cap and turning it to the left (counter-clockwise).
- **Do not** throw away the child-resistant bottle cap.



### Step 3

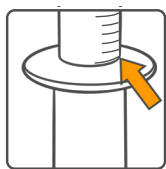
- Place the open bottle on a flat surface.
- Firmly insert the bottle adapter into the bottle by pushing it tightly into the top of the bottle. The top edge of the bottle adapter should be even with the bottle top.
- **Do not** remove the bottle adapter after it is inserted into the bottle.
- Write the date of first opening on your AGAMREE bottle when you first open it.

## ADDITIONAL IMPORTANT SAFETY INFORMATION

### What is the most important information I should know about AGAMREE?

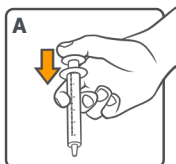
- **Do not stop AGAMREE, or change the amount taken, without first checking with your healthcare provider.** There may be a need for gradual dose reductions to decrease the risk of adrenal insufficiency crisis, which can be fatal.

## Preparing & Withdrawing the AGAMREE® Dose



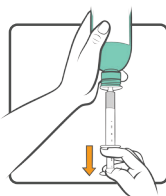
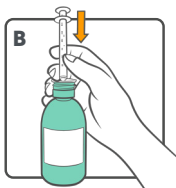
### Step 4

- Check your dose in milliliters (mL) as prescribed by your healthcare provider. Each mark on the oral syringe is equal to 0.1 mL.
- **Do not** take more than the prescribed daily dose.



### Step 5

- Place the bottle on a flat surface.
- Before inserting the tip of the oral syringe into the bottle adapter, push plunger completely down toward the tip of the oral syringe (A).
- Use 1 hand to hold the bottle upright. Insert the oral syringe tip firmly into the opening of the bottle adapter (B).



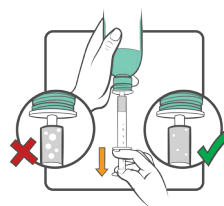
### Step 6

- Hold the oral syringe in place and carefully turn the bottle upside down.
- 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.

### ADDITIONAL IMPORTANT SAFETY INFORMATION

#### What is the most important information I should know about AGAMREE?

- **Corticosteroids, including AGAMREE, can cause severe behavioral and mood changes.** Seek medical attention if behavioral or mood changes develop.



### Step 7

- If there are large bubbles in the oral syringe or if you draw up the wrong dose, 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 you draw up the wrong dose of AGAMREE.



### Step 8

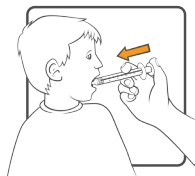
- Leave the tip of the oral syringe in the bottle and turn the entire bottle to an upright position. Slowly remove the oral syringe tip from the bottle by pulling the oral syringe straight up.
- **Do not** hold the oral syringe by the plunger, because the plunger may come out.
- **Take or give AGAMREE right away after it is drawn up into the oral syringe.**
- **Do not** store the filled oral syringe.

### ADDITIONAL IMPORTANT SAFETY INFORMATION

#### What is the most important information I should know about AGAMREE?

- **There is an increased risk of infection when taking corticosteroids like AGAMREE.** Tell your healthcare provider if the patient has had recent or ongoing infections or has recently received a vaccine. Seek immediate medical advice in the case of fever or other signs of infection. Some infections can be severe, and sometimes fatal. Patients should avoid exposure to chickenpox or measles; alert your healthcare provider immediately if exposure occurs.

## Taking or Giving AGAMREE®



### Step 9

- The child or adult should sit upright to take a dose of AGAMREE.
- Place the oral syringe tip in the mouth towards the cheek and slowly push the plunger down until the oral syringe is empty.
- **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.

### Step 10

- If your prescribed dose is greater than 5 mL, repeat **Steps 4 to 9**.

## After Taking or Giving AGAMREE



### Step 11

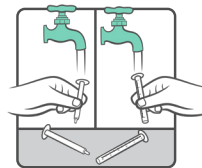
- Put the child-resistant bottle cap back on the bottle and turn the cap to the right (clockwise) to close the bottle. Keep the bottle tightly closed after each use. Store the bottle upright, and refrigerate after opening.

### ADDITIONAL IMPORTANT SAFETY INFORMATION

What is the most important information I should know about AGAMREE?

- **Corticosteroids, including AGAMREE, can cause an increase in blood pressure and water retention.** Your healthcare provider may monitor for these increases during treatment.

## Cleaning the Oral Syringes



### Step 12

- Remove the plunger from the barrel of the oral syringe.
- Rinse the barrel and plunger with running warm water only and let them air dry on a paper towel.
- 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.

### ADDITIONAL IMPORTANT SAFETY INFORMATION

What is the most important information I should know about AGAMREE?

- **There is an increased risk of developing a hole in the stomach or intestines** in patients with certain gastrointestinal disorders when taking corticosteroids like AGAMREE.
- **There is a risk of osteoporosis with prolonged use of corticosteroids like AGAMREE**, which can lead to vertebral and long bone fractures.
- **Corticosteroids like AGAMREE may cause cataracts or glaucoma.** Your healthcare provider should monitor for these conditions if AGAMREE treatment continues for more than 6 weeks.
- Immunizations should be up to date according to immunization guidelines prior to starting therapy with AGAMREE. **Live-attenuated or live vaccines should be administered at least 4 to 6 weeks prior to starting AGAMREE. Live-attenuated or live vaccines should not be administered in patients taking AGAMREE.**
- **Rare instances of severe allergic reaction have occurred** in patients receiving corticosteroid therapy.



For more information, visit  
[www.YourCatalystPathways.com](http://www.YourCatalystPathways.com)  
or call **1-888-4CATALYST** (1-833-422-8259)

## **ADDITIONAL IMPORTANT SAFETY INFORMATION**

**Before taking AGAMREE, tell your healthcare provider about all medical conditions, including if the patient:**

- has decreased liver function
- is pregnant or planning to become pregnant. AGAMREE can harm an unborn baby.
- is breastfeeding or planning to breastfeed. AGAMREE may appear in breastmilk and could affect a nursing child.

**Certain medications can cause an interaction with AGAMREE.**

Tell your healthcare provider about all the medicines the patient takes, including prescription and over-the-counter medicines, dietary supplements, and herbal products.

**What are the possible side effects of AGAMREE?**

The most common side effects with AGAMREE include facial puffiness (cushingoid features), psychiatric disorders, vomiting, weight gain, and vitamin D deficiency. These are not all the possible side effects of AGAMREE.

Call your doctor for medical advice about side effects.

To report SUSPECTED ADVERSE REACTIONS, contact Catalyst Pharmaceuticals, Inc. at 1-844-347-3277 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).



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**Please see Important Safety Information throughout and accompanying full Prescribing Information in pocket.**