Catalyst PATHWAYS®

ENROLLMENT FORM INSTRUCTIONS

The path to Catalyst Pathways® support starts with a completed Enrollment Form

Catalyst Pathways is a comprehensive program that assists patients and their families throughout their treatment journey. It can help your patients receive delivery of AGAMREE® (vamorolone) oral suspension 40 mg/mL, determine insurance coverage, understand out-of-pocket costs, and access a variety of educational resources.

Signup can be completed in three easy steps:

STEP 1

Complete the Enrollment Form in its entirety.

- Sections 1 and 2 can be filled out by the patient/caregiver or the prescriber.
- Sections 3, 4, and 5 should be filled out by the prescriber.
  - Section 4 is the prescription (Rx) and should be filled out according to the label on the AGAMREE® package insert.
  - Section 5 includes Medical Criteria that should be filled out by the prescriber. This section validates the patient's diagnosis.
- Prescriber must sign and date where indicated on page 1.
- Patient/caregiver must sign and date where indicated on page 1.
- Please include a copy of the patient's insurance card (front and back).

Catalyst Pathways provides helpful educational materials and one-on-one dosing support to help ensure that patients achieve their optimal therapeutic dose. If there are delays in verifying your patients' insurance coverage, they may be eligible to receive up to 60 days of free medication under the Catalyst Bridge program.

STEP 2

The patient/caregiver must sign and date the Patient Authorization of the Enrollment Form (Section 6 on page 2) to be enrolled in Catalyst Pathways.

This step is necessary in order for Catalyst Pathways personnel to communicate with the patient's healthcare provider, insurance company, and financial assistance organizations (as necessary).

STEP 3

Fax the signed Enrollment Form to Catalyst Pathways at 1-888-981-9881.

If you have any questions, please call us at
1-833-4-CATALYST (1-833-422-8259)
7:00 AM – 7:00 PM Central Time

Catalyst PATHWAYS®

ENROLLMENT FORM

AGAMREE® (vamorolone) oral suspension 40 mg/mL

Fax #: 1-888-981-9881
Phone #: 1-833-4-CATALYST
(1-833-422-8259)
*Please submit both pages

SECTION 1 - Patient Information (to be filled in by prescriber or patient/caregiver)

Last Name: _____ First Name: _____ DOB: _____ Sex: _____

Address: _____ City: _____ State: _____ ZIP: _____

Phone (please check preferred): ☐ Home: (___)_____ ☐ Work: (___)_____ ☐ Cell: (___)_____

Caregiver Name: _____ Relationship to Patient: _____ Phone #: (___)_____

Emergency Contact: _____ Phone #: (___)_____

SECTION 2 - Insurance Information (to be filled in by prescriber or patient/caregiver). Please fax copies of the patient's insurance card (front and back).

☐ Patient Uninsured Primary Insurance Company Name: _____ Phone #: (___)_____

Policyholder Name: _____ Policy #: _____ Group #: _____

Prescription Card Name: _____ Phone #: (___)_____

Policy #: _____ Group #: _____

Secondary Insurance Company Name: _____ Phone #: (___)_____

Policyholder Name: _____ Policy #: _____ Group #: _____

SECTION 3 - Prescriber Information (to be filled in by prescriber only)

Prescriber Name: _____ NPI: _____ DEA: _____

Address: _____ Physician Tax ID #: _____

City: _____ State: _____ ZIP: _____ State License #: _____

Name of Contact Person: _____ Phone #: (___) _____ Preferred method of communication:

Prescriber Email: _____ Fax #: (___) _____ ☐ Fax ☐ Phone

SECTION 4 - Rx (to be filled in by prescriber only)

AGAMREE® (vamorolone) oral suspension 40 mg/mL:

Dose:

☐ 6 mg/kg/day: not to exceed the daily maximum dosage of 300 mg (7.5 mL)

☐ Other (mg/kg/day) _____

Route of Administration:

☐ By mouth ☐ G-tube ☐ Other: _____

Days Supply: ☐ 30 ☐ 60 ☐ 90 ☐ Other: _____ **Refills:** _____

- The recommended once-daily starting dosage is 6 mg/kg/day with a maximum dose of 300 mg (7.5 mL).
- The recommended once-daily dosage of AGAMREE in patients with mild to moderate hepatic impairment is 2 mg/kg/day with a maximum daily dose of 100 mg (2.5 mL).
- Decrease dosage gradually when administered for more than one week.
- AGAMREE Oral Suspension should be taken once daily with or without food.

SECTION 5 - Medical Criteria (to be filled in by prescriber only)

☐ ICD-10 Code G71.01

Confirm patient has Duchenne muscular dystrophy (DMD):

☐ Yes ☐ No

Tested for DMD:

☐ Genetic test ☐ Creatine kinase ☐ Muscle biopsy

Height: _____ ☐ cm ☐ in Weight: _____ ☐ kg ☐ lb

Gene therapy: ☐ Yes ☐ No

Exon-skipping therapy: ☐ Current ☐ Discontinued ☐ Never

Corticosteroids (eg, prednisone): ☐ Current ☐ Discontinued ☐ Never

EMFLAZA (deflazacort): ☐ Current ☐ Discontinued ☐ Never

Allergies: _____

By signing below, I certify that (1) the above therapy is medically necessary and in the best interest of the named patient; (2) I have received the appropriate permission from the patient (or the patient's Legal Representative) and met any other applicable legal or regulatory requirements such as those imposed under the Health Insurance Portability and Accountability Act of 1996 and/or state law needed to release the above information to Catalyst Pharmaceuticals, Inc. (Catalyst) and its agents; (3) I have obtained the patient's authorization to release the above information and such other information as may be required by AnovoRx Manufacturer Services, LLC, as Catalyst's agent, and its employees to assist in obtaining coverage for this drug; and (4) I appoint AnovoRx Manufacturer Services, LLC, as my agent for the purpose of conveying this prescription to the appropriate dispensing pharmacy, verifying the patient's insurance coverage for AGAMREE® (vamorolone), providing information regarding payer coverage and benefits and how to prepare prior authorization requests, coverage determination appeals, or other coverage issues, and providing me and my patient with educational and support services associated with AGAMREE® (vamorolone).

Prescriber Signature: sign _____ Date: _____

I have read and agree to the Patient Authorization included on the next page.

Patient/Legal Guardian Signature: sign _____ Date: _____

Signatory's Relationship to Patient: _____

SECTION 6 - Patient Authorization

Please refer to our full Privacy Policy at www.catalystpharma.com/privacy-policy/

Print Patient Name: _____ Date of Birth: _____

By signing this Authorization, I authorize my healthcare providers, health plans, and pharmacy providers and any other custodian of my healthcare records to disclose my personal health information, including, but not limited to, information relating to my medical condition, treatment, care management, and health insurance, as well as all information provided on this form and any information about my prescriptions ("Personal Health Information"), to Catalyst Pharmaceuticals, Inc. and its representatives, agents, contractors, and affiliates (collectively, "Catalyst") in order for Catalyst to provide product support services. I further authorize Catalyst to use and disclose my Personal Health Information to third parties, including, but not limited to, specialty pharmacies, health plans, insurance companies, and patient assistance programs solely for such Catalyst Pathways product support services, including, but not limited to, investigating insurance coverage, providing financial assistance for copay or out-of-pocket payments, eligibility for free medication supply, coordinating delivery of medication and communicating with me by mail, email, or telephone about my medical condition, treatment, care management, and health insurance.

I understand that my Personal Health Information, once disclosed to third parties under this Authorization, may no longer be protected by state and federal privacy laws and could be disclosed by Catalyst as well as other recipients of the information to others not identified in this Authorization as long as it is used for the purposes outlined herein. I understand that signing this Authorization is voluntary but that if I decide not to sign this Authorization, I will not be eligible to join Catalyst Pathways and receive its services and benefits for which I may qualify. I also understand that my treatment, payment, enrollment in a health plan, or eligibility for insurance benefits, including my access to therapy, is not conditioned on my signing this Authorization—only my eligibility for Catalyst Pathways. I understand that I am entitled to a signed copy of this Authorization.

I may choose to cancel this Authorization at any time and stop receiving Catalyst Pathways services, and, if I choose to cancel, I must do so in writing by sending notice of my cancellation to the following address: Catalyst Pathways, c/o AnovoRx Manufacturer Services, LLC, 1710 N Shelby Oaks Dr., #3, Memphis, TN 38134. Catalyst Pathways personnel will convey the cancellation to all of my healthcare providers, health plans, and pharmacy providers that have previously received the Authorization. I also understand, however, that any such cancellation will not apply to any information already used or disclosed based on this Authorization prior to receipt of the cancellation by Catalyst. This Authorization expires five (5) years from the date signed below.

I agree to my enrollment in the Catalyst Copay Card Program; if confirmed as eligible, I understand that Copay Card information will be sent to my specialty pharmacy, along with my prescription and any assistance with my cost-sharing or copayment for AGAMREE® (vamorolone) will be made in accordance with the Program Terms and Conditions. I understand that Catalyst may provide compensation to my pharmacy provider in exchange for data and/or Catalyst Pathways services that the pharmacy provides to me.

(The following checkboxes describe additional voluntary programs in which you may choose to participate.)

check ☐ I acknowledge that by checking this box, I expressly consent to receive text messages from or on behalf of the Catalyst Pathways Patient Support activities at the mobile number(s) that I provide. Not checking this box will only allow Catalyst Pathways to communicate with me through calls, emails, and the mail.

I confirm that I am the subscriber for the mobile telephone number(s) provided, and I agree to notify Catalyst Pathways promptly if any of my numbers change in the future. I understand that my wireless service provider's message and data rates may apply. I understand that I can opt out from future text messages by responding STOP to any text. I also understand that additional text messaging terms and conditions may be provided to me in the future as part of an opt-in confirmation text message.

check ☐ I would like to receive information and educational resources about AGAMREE® (vamorolone), as well as updates from Catalyst Pharmaceuticals. I acknowledge that I may opt out of receiving communications by calling 1-833-4-CATALYST (1-833-422-8259) or unsubscribing at the link provided in future communications.

Email Address: _____

Patient/Legal Guardian Signature: sign _____ Date: _____

I, the patient or legal guardian(s), authorize the following individual(s) to act as my representative(s). These individual(s) have my full permission to obtain and disclose personal and medical information about me to Catalyst and its agents and contractors.

Patient/Legal Guardian Signature: sign _____ Date: _____

Name of Patient Representative: _____ Relationship to Patient: _____

Home Phone #: (____)_____ Mobile #: (____)_____

PLEASE FAX TO 1-888-981-9881

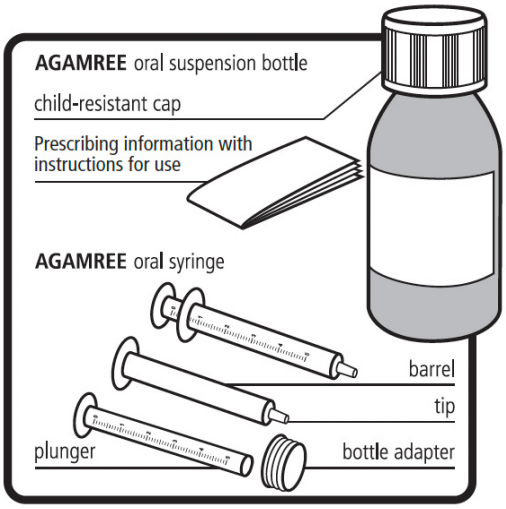
Telephone Inquiries: 1-833-4-CATALYST (1-833-422-8259)

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



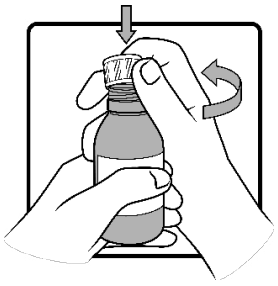
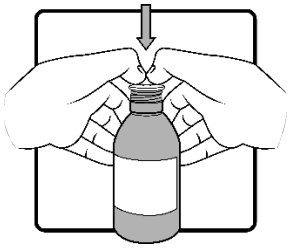
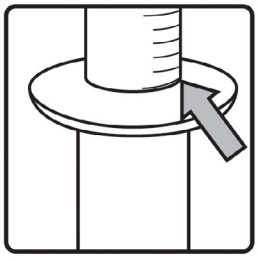
Important information you need to know before taking AGAMREE:

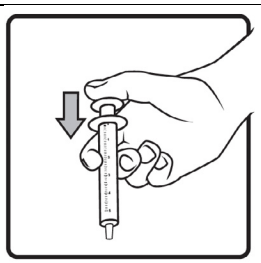
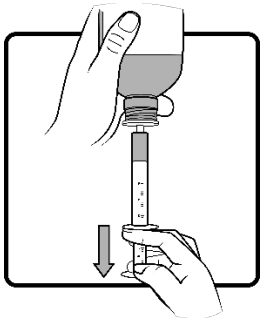
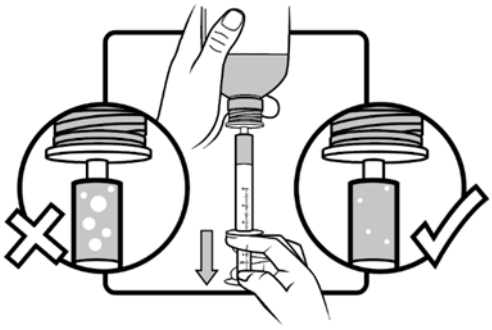
- **For oral use only** (take by mouth).
- **Always use the oral syringes provided with your AGAMREE oral suspension to make sure you measure the right amount.**
- Ask your healthcare provider or pharmacist to show you how to measure your prescribed daily dose using the oral syringe.
- Call your pharmacist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

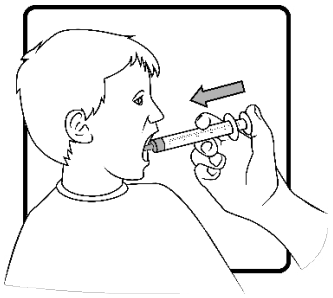
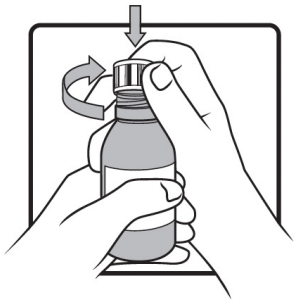
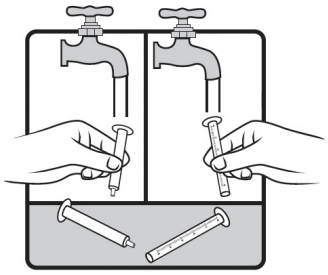
Storing AGAMREE

- 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	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.	
Preparing and withdrawing the AGAMREE dose		
Step 4	Check your dose in millilitres (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 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.	 
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.	
Step 7	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.	
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**.**	

Taking 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.	
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.	

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.
Revised: 03/2024