aGamree®
(vamorolone) oral suspension 40mg/mL

Tough on Duchenne, so it's easier to be him.

GAVEN
Actual AGAMREE patient

Scan to see what makes AGAMREE® different
Or visit AGAMREE.com

FDA-approved 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 on page 19 and full Prescribing Information.

How DMD affects the body

People living with Duchenne muscular dystrophy (DMD) have continuous cycles of muscle damage and repair. These cause inflammation in the muscles. While inflammation is normally a part of the healing process, in DMD, it's ongoing and can cause more damage and weakness to muscles.

This can show up as delayed milestones, difficulty keeping up with other boys who are the same age, frequent falls, an unsteady walk, or difficulty getting up from a lying or sitting position. **As time goes on, other areas of the body may also be affected.**

BRAIN

Boys with DMD may face social, emotional, and behavioral challenges, along with learning difficulties.

HEART

Boys may have an irregular heartbeat, and the heart may have trouble pumping enough blood to meet the body's needs.

BONES

Bones can become weaker, making fractures more likely. Bone fractures can limit the ability to move, leading to muscle weakness over time.

BREATHING MUSCLES

The diaphragm, a muscle that helps control breathing, may eventually be affected. This can lead to the need for assisted breathing.

Scan to see how DMD causes muscle weakness in the body

Or visit AGAMREE.com/about-dmd

Corticosteroids are the standard of care, but may cause side effects

Corticosteroids are commonly used to treat DMD and guidelines show daily dosing is safe and effective. They can help slow the progression of DMD by reducing inflammation and helping muscles stay stronger for longer.

However, these medicines can also cause side effects, which may limit how long or how often they can be used.

- Side effects may include behavior changes, growth delay, bone changes or fractures, puffiness in the face (known as "Cushingoid appearance"), weight gain, increased body hair, and cloudy vision (cataracts)
- These side effects may make it necessary to modify or stop corticosteroid therapy
  - 6 of 10 people with DMD who stop treatment with corticosteroids do so because of side effects

Nearly 4 in 10 boys

HAVE BEHAVIOR CHANGES

May make it necessary to adjust or stop treatment

Up to 7 in 10 boys

MAY HAVE SLOWER GROWTH

Can affect overall well-being and make it harder to stick with treatment

More than 7 in 10 boys

HAVE WEAK BONES OR FRACTURES

Can reduce mobility earlier, and that loss may be permanent

Talk with your healthcare provider about any side effects experienced while taking corticosteroids

AGAMREE® was developed to be different

AGAMREE helps fight inflammation just like the type of steroids commonly used to treat DMD. However, it works in a different way that was developed to help lower the risk of side effects that steroids can sometimes cause.

***Like* other steroids used to treat DMD:**

AGAMREE fights inflammation

It works by lowering the activity of a protein in the body that plays a key role in causing inflammation.

***Unlike* other steroids used to treat DMD:**

AGAMREE was developed to help reduce certain side effects

It's developed to work differently in the body, limiting the activation of glucocorticoid response elements. This may help avoid some of the common side effects caused by regular steroids.

While the way AGAMREE works is not fully understood, it is thought that AGAMREE treats DMD through its strong anti-inflammatory action.

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aGamree® (vamorolone) oral suspension 40mg/mL

"Starting Eli on AGAMREE at three was the best choice we could have made for him. His muscle is precious, and time is muscle."

– Ashlyn, mother of Eli

ELI

Actual AGAMREE patient

"After the trial ended, we were asked to participate in the extension study. We said, 'Absolutely! He's functioning on it. I don't want to take him off it if it's working.'"

– Michelle, mother of Landon

LANDON

Actual AGAMREE patient

Proven through experience

AGAMREE® showed proven results in a study that lasted for 2 back-to-back 24-week periods.

First period: 24 weeks	The first period of the clinical trial was **24 weeks**	Trial included **121 boys** from around the world—all between 4 and 7 years of age	Boys received **1 of 4 treatments** daily: • AGAMREE 6 mg/kg • AGAMREE 2 mg/kg • Prednisone 0.75 mg/kg • Placebo (inactive treatment)	The main measure was **effectiveness** • How fast boys could stand up from lying on their back, assessed using the Time to Stand test
Second period: 24 weeks	The clinical trial was extended for an **additional 24-week period**	The trial extension included **114 boys from the first trial period**	Boys taking AGAMREE stayed on their same dose **Boys taking prednisone or placebo switched to AGAMREE,** with each group split evenly between 6 mg/kg daily and 2 mg/kg daily	The main measures were **safety and effectiveness** • How fast boys could stand up from lying on their back, assessed using the Time to Stand test

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aGamree® (vamorolone) oral suspension 40mg/mL

AGAMREE® improves muscle strength and movement

At 24 weeks, boys taking AGAMREE 6 mg/kg daily:

Stood up faster

0.06 rises/second faster*

Time to Stand Test
Total time it took boys to stand from lying on their back and the speed in which they stood

Walked farther

42 meters farther*

6-Minute Walk Test
Distance boys could walk in 6 minutes

Walked/ran faster

0.24 meters/second faster*

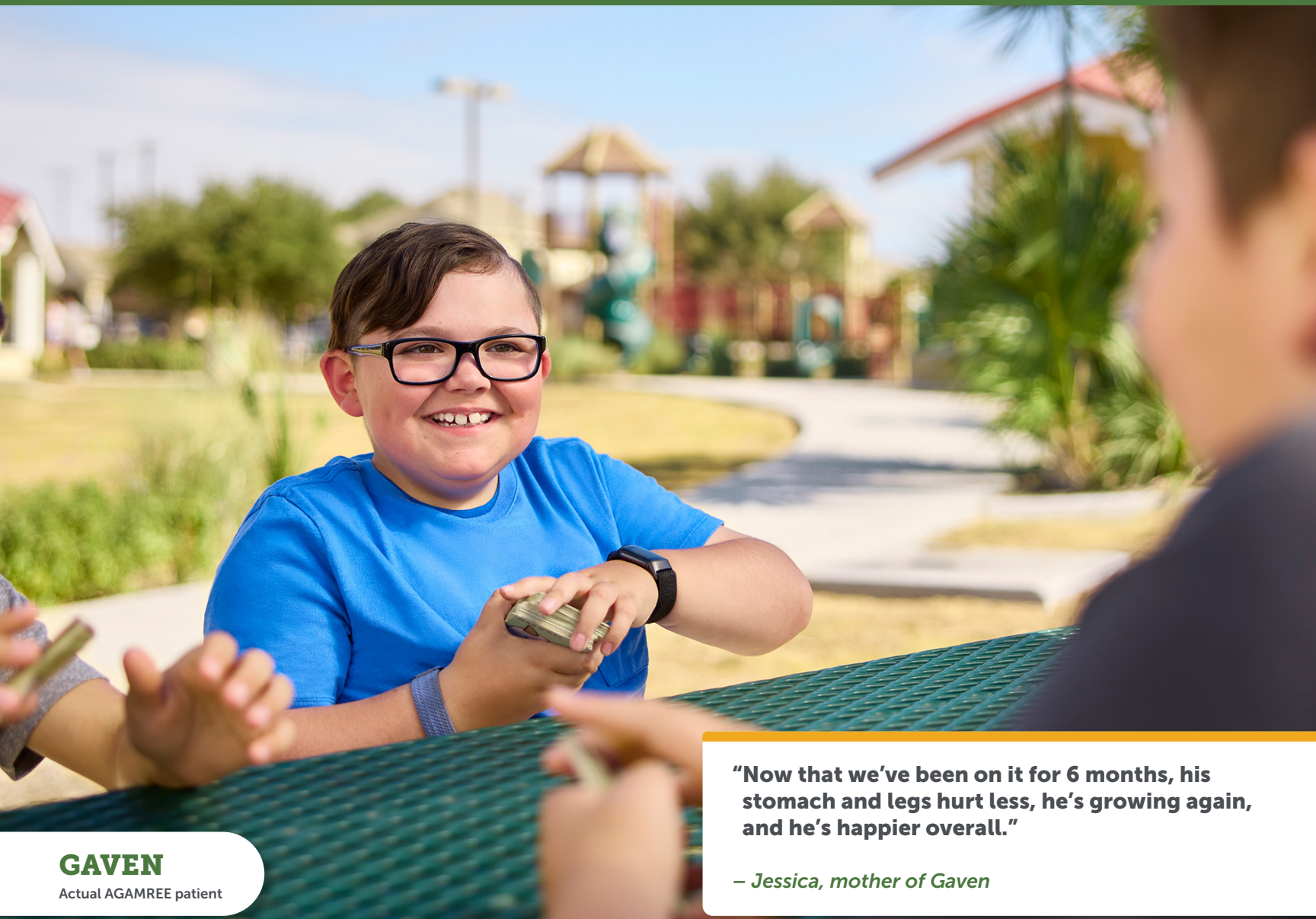
Time to Run or Walk 10 Meters Test
How fast boys could run or walk 10 meters

Results with AGAMREE were maintained over time
These improvements in muscle strength and movement lasted through 48 weeks of treatment

*Compared with placebo.

aGamree® (vamorolone) oral suspension 40mg/mL

Please see Important Safety Information on page 19 and full Prescribing Information.



GAVEN
Actual AGAMREE patient

"Now that we've been on it for 6 months, his stomach and legs hurt less, he's growing again, and he's happier overall."

– Jessica, mother of Gaven

Understanding possible side effects

AGAMREE® was well tolerated in clinical trials, but as with all medicines, side effects are possible. Before starting AGAMREE, ask your healthcare provider about the benefits and risks.

The most common side effects with AGAMREE included:

- Puffiness in the face (sometimes called a "Cushingoid appearance")
- Psychiatric disorders*
- Vomiting
- Weight gain
- Low levels of vitamin D

These are not all the possible side effects of AGAMREE. Call your doctor for medical advice about side effects.

AGAMREE was well tolerated over time
The safety at 48 weeks was similar to 24 weeks

Scan to see the benefits and risks of AGAMREE
Or visit AGAMREE.com/about-agamree

*Includes abnormal behavior, aggression, agitation, anxiety, irritability, personality changes, sleep disorder, and repetitive movements (stereotypy).

Please see Important Safety Information on page 19 and full Prescribing Information.

aGamree® (vamorolone) oral suspension 40mg/mL

Switching from prednisone to AGAMREE may help reduce side effects

In the clinical trial, boys who switched from prednisone to AGAMREE 6 mg/kg had less:

Behavior Problems	Stomach or digestive problems	Puffiness in the face "Cushingoid appearance"	Weakened immune system	Weight Gain
Prednisone **40%**	Prednisone **27%**	Prednisone **20%**	Prednisone **~47%**	Prednisone **13%**
↓	↓	↓	↓	↓
20% AGAMREE	**20%** AGAMREE	**~7%** AGAMREE	**33%** AGAMREE	**~7%** AGAMREE

Switching from prednisone to AGAMREE helped reduce behavior problems in boys

Please see Important Safety Information on page 19 and full Prescribing Information.

Switching from prednisone to AGAMREE® improves measures of bone health, growth, and body size

Bone health

After taking medicine daily for 24 weeks, boys with DMD were evaluated to look at its effects on bone health:

- **AGAMREE did not** show harmful changes to measures of bone health
- **Prednisone showed** harmful changes to measures of bone health

Growth

After taking medicine daily for 24 weeks, boys with DMD were evaluated to look at its effects on growth patterns:

- **Boys taking AGAMREE grew more**—showing an increase in height percentile
- Boys taking prednisone **showed slow growth**

Body mass index

After taking medicine daily for 24 weeks, boys with DMD were evaluated to look at its effects on body mass index—a measure based on height and body weight:

- In the first 24 weeks, body mass index increased in boys taking either prednisone or AGAMREE
- After the first 24 weeks, **body mass index stayed steady through Week 48**

Switching from prednisone to AGAMREE quickly helped improve measures of bone health and helped improve growth patterns in boys who were growing more slowly

Ask your healthcare provider about side effects—both at the start of treatment and over time.

Additional information is needed to understand the longer-term effects of AGAMREE.

aGamree® (vamorolone) oral suspension 40mg/mL

Please see Important Safety Information on page 19 and full Prescribing Information.

"Him being able to tell us that, 'Hey, I feel the best I've felt in a long time,' as a parent, that helps you realize that maybe you did make the right decision."

– Jessica, mother of Gaven

GAVEN

Actual AGAMREE patient, and the Mile Monsters

Taking AGAMREE®

- Convenient once-daily dosing
- Preferably taken with a meal
- Orange-flavored liquid
- Tell your healthcare provider about all medical conditions, and about all medications the patient takes

Patients may switch to AGAMREE from another oral corticosteroid (like prednisone or deflazacort) without treatment interruption or period of prior corticosteroid dosage reduction.

"Gaven likes the taste of AGAMREE. He says it's a citrus flavor."

– Jessica, mother of Gaven

Scan to watch a dosing demonstration
Or visit AGAMREE.com/dosing-and-administration

aGamree® (vamorolone) oral suspension 40mg/mL

Please see Important Safety Information on page 19 and full Prescribing Information.

What should I tell my healthcare provider before starting AGAMREE?

Before starting AGAMREE, tell your healthcare provider about...

All medical conditions
Including if the patient:

- Has decreased liver function
- Is pregnant or planning to become pregnant
- Is breastfeeding or planning to breastfeed

All medications the patient takes

- These may include prescription and over-the-counter medicines, dietary supplements, and herbal products
- Certain medications may cause an interaction with AGAMREE

What else should I know about AGAMREE?

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

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

Please see Important Safety Information on page 19 and full Prescribing Information.

Get a clear path to prompt, affordable treatment

DMD comes with plenty of challenges—accessing and paying for treatment shouldn't be one of them. That's why we created Catalyst Pathways®—a free program offering personalized support and assistance to people living with DMD and their families.

Access to treatment

Catalyst Bridge program helps cover access delays

While your insurance coverage is being reviewed, Catalyst Pathways can provide qualifying patients with free medicine to carry eligible patients over the gap between insurance investigation and confirmation of coverage.*

Cost support

<$2 per month: Average monthly out-of-pocket cost
$0 per month: Qualifying commercial patients

Average co-pay cost represents the latest data on file.

Patient assistance program

If you do not have insurance or are denied coverage, Catalyst Pathways provides **free medicine to qualifying patients for as long as it's needed**.

Foundation assistance

If you're having trouble paying your out-of-pocket costs, Catalyst Pathways can direct you to nonprofit organizations that can help you pay for your medicine.

*Available for new patients with DMD who are enrolled in the Catalyst Pathways program and have been prescribed AGAMREE. Some restrictions apply.

Please see Important Safety Information on page 19 and full Prescribing Information.

Support and guidance

Catalyst Pathways® features a dedicated team of support specialists who have the answers you're looking for and are trained to troubleshoot any issues that may arise.

Care Coordinators

Provides a warm welcome, passes along need-to-know information, and connects you to your dedicated team.

Insurance Navigators

Handles complicated coverage and reimbursement issues and works to resolve them.

Patient Access Liaisons (PALs)

Your go-to, local resource for education and treatment support when and where you need it.

"Immediately after starting AGAMREE®, we were introduced to Catherine, our patient access liaison, who helped walk us through everything."

– Jessica, mother of Gaven

Scan to enroll in Catalyst Pathways
Or call 1-833-4-CATALYST (1-833-422-8259)

Please see Important Safety Information on page 19 and full Prescribing Information.

Catalyst PATHWAYS®

LANDON

Actual AGAMREE patient, and his parents Michelle & Gil

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.

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.
- **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.
- **Corticosteroids, including AGAMREE, can cause an increase in blood pressure and water retention.** Your healthcare provider may monitor for these increases during treatment.
- **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.
- **Corticosteroids, including AGAMREE, can cause severe behavioral and mood changes.** Seek medical attention if behavioral or mood changes develop.
- **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.

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.

Please see full Prescribing Information for additional Important Safety Information.

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.

Give your child with DMD the strength to be a kid

aGamree® (vamorolone) oral suspension 40mg/mL

Talk to your healthcare provider

Be prepared for your next conversation by taking notes on symptoms and how they are affecting daily activities. It's also important to include any questions you may have for your healthcare provider.

Scan for 6 ways to help improve your conversations

Or visit AGAMREE.com/starting-agamree

Meet boys taking AGAMREE®

Hear how AGAMREE has impacted lives—from actual AGAMREE patients and their families.

Scan to watch their stories

Or visit AGAMREE.com/patient-support/agamree-resources

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Catalyst pharmaceuticals