aGamree®
(vamorolone) oral suspension 40mg/mL

Quick Dosing Guide

- Orange-flavored oral suspension with once-daily dosing
- Switch from current corticosteroid therapy without interruption or dose reduction

Scan to consult the full Prescribing Information for AGAMREE®

INDICATIONS AND USAGE

AGAMREE is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.

IMPORTANT SAFETY INFORMATION

Contraindications

AGAMREE is contraindicated in patients with known hypersensitivity to vamorolone or any of the inactive ingredients in AGAMREE.

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

Straightforward Once-Daily Dosing

AGAMREE Dosage

6 mg/kg

Up to 300 mg/d for patients weighing >50 kg

The recommended dosage of AGAMREE® is 6 mg/kg taken orally once daily, preferably with a meal, up to a maximum daily dosage of 300 mg for patients weighing >50 kg

Some patients may respond to a dose of 2 mg/kg/d; doses may be titrated down to 2 mg/kg/d as needed, based on individual tolerability.

- In patients with mild to moderate hepatic impairment, the recommended dosage is 2 mg/kg taken orally once daily, preferably with a meal, up to a maximum daily dosage of 100 mg for patients weighing >50 kg
- When used concomitantly with strong CYP3A4 inhibitors, the recommended dosage is 4 mg/kg taken orally once daily, preferably with a meal, up to a maximum daily dosage of 200 mg for patients weighing >50 kg

Switching to AGAMREE

Patients switching after long-term treatment with oral corticosteroids should start AGAMREE at a dosage of 6 mg/kg/d.*

*Patients can be switched from oral corticosteroid treatment (eg, prednisone or deflazacort) to AGAMREE without treatment interruption or period of prior corticosteroid dosage reduction to minimize the risk of adrenal insufficiency.

ADDITIONAL IMPORTANT SAFETY INFORMATION

Adverse Reactions

The most common adverse reactions (>10% for AGAMREE and greater than placebo) are cushingoid features, psychiatric disorders, vomiting, weight increased, and vitamin D deficiency.

Use in Specific Populations

- In patients with mild to moderate hepatic impairment, the recommended daily dose of AGAMREE is 2 mg/kg preferably with a meal, up to a maximum daily dosage of 100 mg for patients weighing more than 50 kg.
- When used concomitantly with strong CYP3A4 inhibitors, the maximum recommended daily dose of AGAMREE is 4 mg/kg preferably with a meal, up to a maximum daily dosage of 200 mg for patients weighing more than 50 kg.
- The safety and effectiveness of AGAMREE have not been established in pediatric patients below the age of 2 years.

Calculating the Daily Dose

Example calculation

Calculate the dose in mg

Convert weight in lb to kg

Recommended AGAMREE dosage: **6 mg/kg/d**

6 mg/kg/d x 20 kg = 120 mg/d

Convert the dose to mL

AGAMREE is available as a **40 mg/mL** oral suspension

$$\frac{120 \text{ mg/d}}{40 \text{ mg/mL}} = 3 \text{ mL/d}$$

Refer patients to the Instructions for Use for detailed guidance on preparation and administration.

Indicate the dose in mL on the prescription to help ensure accurate administration

ADDITIONAL IMPORTANT SAFETY INFORMATION

Warnings & Precautions

- **Alterations in Endocrine Function:** Corticosteroids, such as AGAMREE, can cause serious and life-threatening alterations in endocrine function, especially with chronic use. Monitor patients receiving AGAMREE for Cushing's syndrome, hyperglycemia, and adrenal insufficiency after AGAMREE withdrawal. In addition, patients with hypopituitarism, primary adrenal insufficiency or congenital adrenal hyperplasia, altered thyroid function, or pheochromocytoma may be at increased risk for adverse endocrine events. Acute adrenal insufficiency can occur if AGAMREE is withdrawn abruptly, and could be fatal. The risk of adrenal insufficiency is reduced by gradually tapering the dose when withdrawing treatment. For patients already taking corticosteroids during times of stress, the dosage may need to be increased.
- **Immunosuppression and Increased Risk of Infection:** Use of corticosteroids, including AGAMREE, increases the risk of new infection, exacerbation of existing infections, dissemination, and reactivation or exacerbation of latent infection and may mask some signs of infection; these infections can be severe, and at times fatal. Tell patients and/or caregivers to inform their healthcare provider if the patient has had recent or ongoing infections or has recently received a vaccine. Advise patients taking AGAMREE to avoid exposure to chickenpox or measles and to alert their healthcare provider immediately if they are exposed.

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Get Your Patients Started on AGAMREE®

- Complete the AGAMREE Enrollment Form
- Have the patient sign the Patient Authorization section
- Fax the signed form to Catalyst Pathways® at 1-888-981-9881

Scan to Download Enrollment Form

For questions, contact Catalyst Pathways at 1-833-4-CATALYST (1-833-422-8259)

ADDITIONAL IMPORTANT SAFETY INFORMATION

Warnings & Precautions

- **Alterations in Cardiovascular/Renal Function:** Monitor for elevated blood pressure and monitor sodium and potassium levels in patients chronically treated with AGAMREE.
- **Gastrointestinal Perforation:** Use of corticosteroids increases the risk of gastrointestinal perforation in patients with certain gastrointestinal disorders, such as active or latent peptic ulcers, diverticulitis, fresh intestinal anastomoses, and non-specific ulcerative colitis. Signs and symptoms of gastrointestinal perforation may be masked.
- **Behavioral and Mood Disturbances:** Potentially severe psychiatric adverse reactions may occur with systemic corticosteroids, including AGAMREE, and may include hypomanic or manic symptoms (eg, euphoria, insomnia, mood swings) during treatment and depressive episodes after discontinuation of treatment. Encourage patients to seek medical attention if psychiatric symptoms develop.
- **Effects on Bones:** Prolonged use of corticosteroids, such as AGAMREE, can lead to osteoporosis, which can predispose patients to vertebral and long bone fractures. Monitor bone mineral density in patients on long-term treatment with AGAMREE.
- **Ophthalmic Effects:** The use of corticosteroids, such as AGAMREE, may increase the risk of cataracts, ocular infections, and glaucoma. Monitor intraocular pressure if treatment with AGAMREE is continued for more than 6 weeks.
- **Vaccination:** Do not administer live-attenuated or live vaccines to patients receiving AGAMREE. Administer live-attenuated or live vaccines at least 4 to 6 weeks prior to starting AGAMREE.
- **Effects on Growth and Development:** Long-term use of corticosteroids, including AGAMREE, can have negative effects on growth and development in children.
- **Thromboembolic Events:** Observational studies have shown an increased risk of thromboembolism. Use AGAMREE with caution in patients who have or may be predisposed to thromboembolic disorders.

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.

Catalyst pharmaceuticals

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