PATIENT & CAREGIVER EDUCATION

Vamorolone

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Agamree

Brand Names: Canada

Agamree

What is this drug used for?

- It is used to treat Duchenne muscular dystrophy (DMD).

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have any infection, including a fungal infection, malaria infection in the brain, amoeba infection like traveler's diarrhea, or herpes infection of the eye.

- If you have any stomach or bowel problems. This includes diverticulitis, ulcerative colitis, ulcers, or recent bowel surgery.
- If you have liver disease.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Have your blood work and other lab tests checked as you have been told by your doctor.
- High blood sugar has happened with this drug. This includes diabetes that is new or worse.
- Check your blood sugar as you have been told by your doctor.

- Make sure you are up to date with all your vaccines before treatment with this drug. Talk with your doctor to find out when you need to get any vaccines before starting this drug.
- You may have more of a chance of getting an infection. Some infections with drugs like this one can be severe and rarely deadly. Wash hands often. Stay away from people with infections, colds, or flu.
- Chickenpox and measles can be very bad or even deadly in some people taking steroid drugs like this drug. Avoid being near anyone with chickenpox or measles if you have not had these health problems before. If you have been exposed to chickenpox or measles, talk with your doctor.
- If you have had hepatitis B before or carry the virus, talk with your doctor. This drug can cause the virus to become active again.
- Hepatitis B testing needs to be done as you were told by the doctor. Talk with the doctor.
- If you have TB (tuberculosis), talk with your doctor.
- If you have threadworms, talk with your doctor. Drugs like this one can cause threadworms to spread which may be deadly.
- High blood pressure has happened with drugs like this

one. Have your blood pressure checked as you have been told by your doctor.

- This drug may cause weak bones (osteoporosis) with long-term use. Talk with your doctor to see if you have a higher chance of weak bones or if you have any questions.
- Long-term use may raise the chance of cataracts or glaucoma. Talk with the doctor.
- Have your eye pressure checked if you are on this drug for a long time. Talk with your doctor.
- Steroid drugs like this one can cause certain health problems with hormones in the body, especially with long-term use. These health problems can be severe or life-threatening. This includes changes in adrenal gland function and a tumor on the adrenal gland (pheochromocytoma). Talk with your doctor if you have any thyroid, pituitary, or adrenal gland problems.
- Health problems like Cushing's syndrome and weak adrenal gland can happen after stopping this drug. Do not stop taking this drug all of a sudden without talking to your doctor. You may need to slowly stop it as ordered by your doctor.
- The risk of muscle problems may be raised with the use of drugs like this one in people who already have nerve

or muscle problems like myasthenia gravis. The risk may also be raised in people who are getting drugs used to relax muscles while on a breathing machine or during surgery. If you have questions, talk with the doctor.

- A type of cancer (Kaposi's sarcoma) has happened in people taking drugs like this one for a long time. Talk with the doctor.
- This drug may affect growth in children and teens in some cases. They may need regular growth checks. Talk with the doctor.
- Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or

swelling of the mouth, face, lips, tongue, or throat.

- Signs of a weak adrenal gland like a severe upset stomach or throwing up, severe dizziness or passing out, muscle weakness, feeling very tired, mood changes, decreased appetite, or weight loss.
- Signs of Cushing's syndrome like weight gain in the upper back or belly, moon face, severe headache, or slow healing.
- Signs of high blood sugar like confusion, feeling sleepy, unusual thirst or hunger, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Signs of electrolyte problems like mood changes; confusion; muscle pain, cramps, or spasms; weakness; shakiness; change in balance; an abnormal heartbeat; seizures; loss of appetite; or severe upset stomach or throwing up.
- Shortness of breath, a big weight gain, or swelling in the arms or legs.

- Change in eyesight.
- Bone or joint pain.
- Black, tarry, or bloody stools.
- Throwing up blood or throw up that looks like coffee grounds.
- Severe stomach pain.
- Mental, mood, or behavior changes that are new or worse.
- Trouble sleeping.
- Call your doctor right away if you have signs of a blood clot like chest pain or pressure; coughing up blood; shortness of breath; swelling, warmth, numbness, change of color, or pain in a leg or arm; or trouble speaking or swallowing.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Throwing up.
- Weight gain.
- Headache.

- Diarrhea.
- Increased appetite.
- Runny nose.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1- 800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take by mouth only.
- Take with a meal.
- Shake well for at least 30 seconds before each use.
- Measure liquid doses carefully. Use the measuring device that comes with this drug. If there is none, ask the pharmacist for a device to measure this drug.
- Do not mix with other liquids.

- Each oral syringe that comes with this drug can be used for 45 days. Talk to your pharmacist if you need more syringes.
- Put this drug right into the mouth using the measuring device.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it, with a meal.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store unopened bottles at room temperature.
- Store in the outer carton.
- Store upright with the cap on.
- After opening, store upright in a refrigerator. Do not freeze. Throw away any part not used after 3 months.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.

- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms.

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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