

90 MM

90 MM

90 MM

90 MM

90 MM

90 MM

90 MM

72 MM

50 MM

478 MM

Package leaflet: Information for the patient**AGAMREE****40 mg/ml
oral suspension
vamorolone**

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET

1. What AGAMREE is and what it is used for
2. What you need to know before you take AGAMREE
3. How to take AGAMREE
4. Possible side effects
5. How to store AGAMREE
6. Contents of the pack and other information

1. What AGAMREE is and what it is used for

AGAMREE is a steroidal anti-inflammatory medicine that contains the active substance vamorolone.

AGAMREE is used to treat patients aged 4 years and older with Duchenne muscular dystrophy (DMD). DMD is a genetic condition caused by defects in the dystrophin gene, which normally makes a protein that keeps muscles healthy and strong. In patients with DMD, this protein is not generated and the body is unable to grow new muscle cells or replace damaged muscle. This causes the muscles of the body to become weaker over time.

AGAMREE is used to stabilize or improve muscle strength in patients with DMD.

2. What you need to know before you take AGAMREE**Do not take AGAMREE**

- if you are allergic to vamorolone or any of the other ingredients of this medicine (listed in section 6)
- if you have a severe liver problem
- if you plan to have or have had any vaccination with live or live attenuated vaccines (such as Measles, Mumps, Rubella or Chickenpox) in the last 6 weeks. Talk to your doctor if you are already being treated with AGAMREE and planning such vaccination.

Warnings and precautions

Talk to your doctor before using AGAMREE

Alterations in endocrine function: adrenal insufficiency

AGAMREE reduces the amount that your body can produce of a hormone called cortisol. This is called adrenal insufficiency.

- you should not reduce the amount of AGAMREE or stop taking AGAMREE without talking to your doctor; if you abruptly reduce or stop taking AGAMREE for a few days, you may develop symptoms of acute adrenal insufficiency such as excess fatigue, dizziness or confusion, which may be life-threatening; your doctor may have to monitor your treatment more closely if you change the dose.
- if you are under unusual stress (such as acute infection, traumatic injuries or a major surgical procedure), you may need to take an additional steroidal medicine to prevent acute adrenal insufficiency. Discuss with your doctor what to do in case of unusual stress before starting AGAMREE

- if you are being treated with another corticosteroid such as prednisone, you will be able to switch to AGAMREE from one day to the other, but your doctor will advise you on the dose of AGAMREE that you should take.
- if you have a type of tumor in your adrenal glands called pheochromocytoma, your doctor may have to monitor your treatment more closely

IMPORTANT: The AGAMREE pack includes a Patient Alert Card which contains important safety information about adrenal crisis. Keep this card with you at all times.

Weight gain

- AGAMREE may increase your appetite and therefore your weight, mainly in the first months of treatment; your doctor or nurse will give you dietary advice before and during treatment.

Patients with altered thyroid function

- if you have hypothyroidism (an underactive thyroid) or hyperthyroidism (an overactive thyroid), your doctor may have to monitor your treatment more closely, or change your dose.

Ophthalmic effects

- if you or somebody in your family has glaucoma (increased pressure in the eye), your doctor may have to monitor your treatment more closely

Increased risk of infections

AGAMREE may reduce your natural resistance to infections.

- if you have a lowered immune response (due to an immunodeficiency syndrome, a disease or due to other medicines that suppress the immune system), your doctor may have to monitor your treatment more closely
- if you experience an infection while on treatment with AGAMREE, your doctor may have to monitor you more closely and you may require treatment with an additional steroidal medicine
- AGAMREE use over years may increase the probability that you develop diabetes mellitus (a sugar related disease); your doctor may check your sugar levels regularly.

Vaccination

- if you plan to receive a vaccination with live attenuated or live vaccines, this should occur at least 6 weeks prior to starting AGAMREE treatment.
- if you have never had chickenpox or have not been vaccinated against chickenpox, you may discuss vaccination with your doctor before starting AGAMREE.

Thromboembolic events

- if you have had thromboembolic events (a blood clot inside your body) or a disease that increase your risk to have blood clotting, your doctor may have to monitor your treatment more closely.

Hepatic impairment

- if you have liver disease, your doctor may have to change your dose.

Children

Do not give AGAMREE to children under the age of 4 years as it has not been tested in this group of patients.

Other medicines and AGAMREE

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tell your doctor if you are taking any of the following medicines:

- Medicines used to treat seizures and neuropathic pain, such as carbamazepine or phenytoin as these can influence the effect of the medicine
 - Medicines used to treat fungal infections (including candidiasis and aspergillosis) known as triazoles, such as itraconazole and voriconazole, as these can influence the effect of the medicine
 - Antibiotics known as macrolides (such as clarithromycin) or "ketolides" (such as telithromycin), as these can influence the effect of the medicine
 - Antibiotics known as rifamycins, such as rifampicin, as these can influence the effect of the medicine
 - Spironolactone or spironolone, known as potassium-sparing diuretic treatments (treatments that increase urine production), which may be used to lower blood pressure and protect cardiovascular function as they may have some similar effects as AGAMREE; your doctor may have to monitor your potassium levels and change the dose of these medicines
 - St John's wort (*Hypericum perforatum*), a herbal medicine used to treat depression and emotional disorders, as these can influence the effect of the medicine
- If you need to receive a vaccine, seek your doctor's advice first (see section 2: "Do not take AGAMREE"). You should not receive certain types of vaccine (live or live-attenuated vaccines) from up to 6 weeks before starting treatment with AGAMREE, as in this combination, these vaccines could trigger the infection that they are supposed to prevent.

AGAMREE with food and drink

Avoid grapefruit and grapefruit juice during treatment with AGAMREE, as these can influence the effect of the medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

If you are pregnant, you should not use AGAMREE unless clearly indicated by your doctor.

If you are a woman who could become pregnant, you have to use effective contraception during treatment with AGAMREE.

Animal studies have shown that long-term treatment with AGAMREE may impair male and female fertility.

Driving and using machines

Discuss with your doctor whether your illness allows you to drive vehicles, including a bicycle, and use machines safely. AGAMREE is not expected to affect the ability to drive, cycle or use machines.

AGAMREE contains sodium benzoate and sodium

AGAMREE contains 1 mg sodium benzoate (E211) in each ml. AGAMREE contains less than 23 mg of sodium per 7.5 ml and is essentially 'sodium-free'.

3. How to take AGAMREE

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of AGAMREE depends on your body weight and your age.
If you are 4 years or older and your weight is less than 40 kg, the dose is usually 6 mg per kg body weight, taken once a day.

If you are 4 years or older and your weight is 40 kg or more, the dose of is usually 240 mg, taken once a day.

If you get certain side effects while you are taking AGAMREE (see section 4), your doctor may lower your dose or stop treatment temporarily or permanently. Your doctor may reduce your dose if you suffer from liver disease.

This medicine is taken by mouth. AGAMREE can be taken with or without a meal (see section 2 "AGAMREE with food and drink").

To withdraw the medicine, use one of the oral syringes included in the pack. Use only these oral syringes when measuring out your dose. Your doctor will tell you how much you need to withdraw with the syringe for your daily dose.

Caregivers should provide assistance with the administration of AGAMREE, particularly with regards to the use of oral syringes to measure and administer the prescribed dose.

Shake the bottle well before withdrawing with the syringe. Withdraw your dose into the oral syringe, then immediately and slowly empty the syringe directly into your mouth. Please read the instructions below for more information about how to measure and take the dose correctly. Check with your doctor or pharmacist if you are unsure how to use the oral syringe.

After taking your prescribed dose, disassemble the oral syringe, rinse the syringe and plunger under running cold tap water and air dry. Store the cleaned oral syringe in the pack until next use. An oral syringe should only be used for up to 45 days. After this time, discard it and use the second oral syringe provided in the pack. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

HOW TO PREPARE YOUR DOSE OF AGAMREE ORAL SUSPENSION**BEFORE TAKING/GIVING AGAMREE**

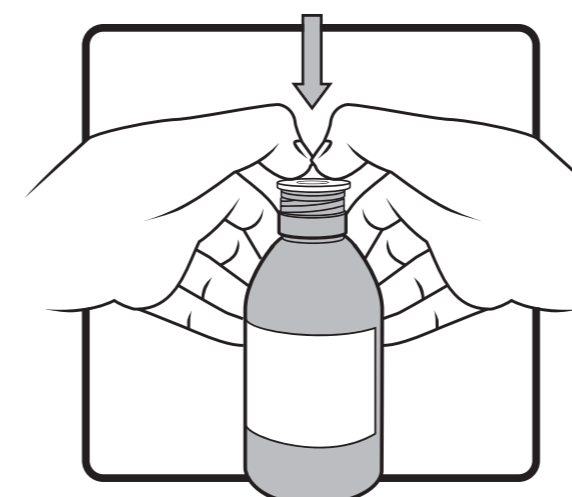
Step 1. Make sure the child-resistant bottle cap is tightly secured and shake the bottle well.



Step 2. Remove the child-resistant bottle cap by pushing it firmly down and turning it counter clockwise.



Step 3. Firmly insert the bottle adapter into the bottle.



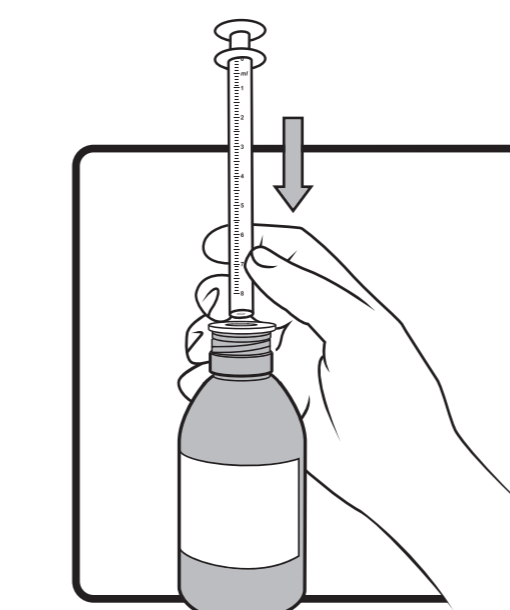
This is to be done the first time that you open the bottle. The adapter must thereafter stay in the bottle.

If you drop the bottle adapter, clean it under cold running water and air dry for at least 2 hours.

PREPARING A DOSE OF AGAMREE

Step 4. Hold the bottle upright.

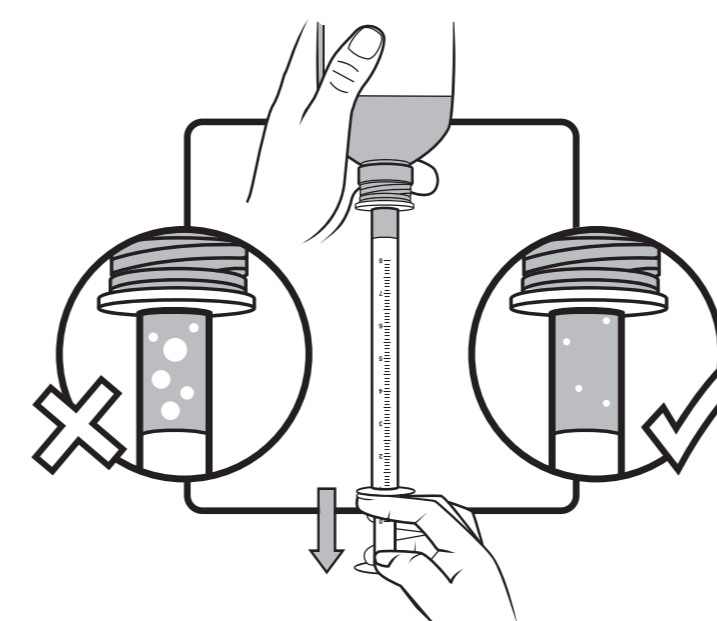
Before inserting the tip of the oral syringe into the bottle adapter, push the plunger completely down toward the tip of the oral syringe. Insert the tip firmly into the opening of the bottle adapter



Step 5. Hold the oral syringe in place and carefully turn the bottle upside down.

Pull the plunger out slowly until the desired amount of medicine is withdrawn into the oral syringe.

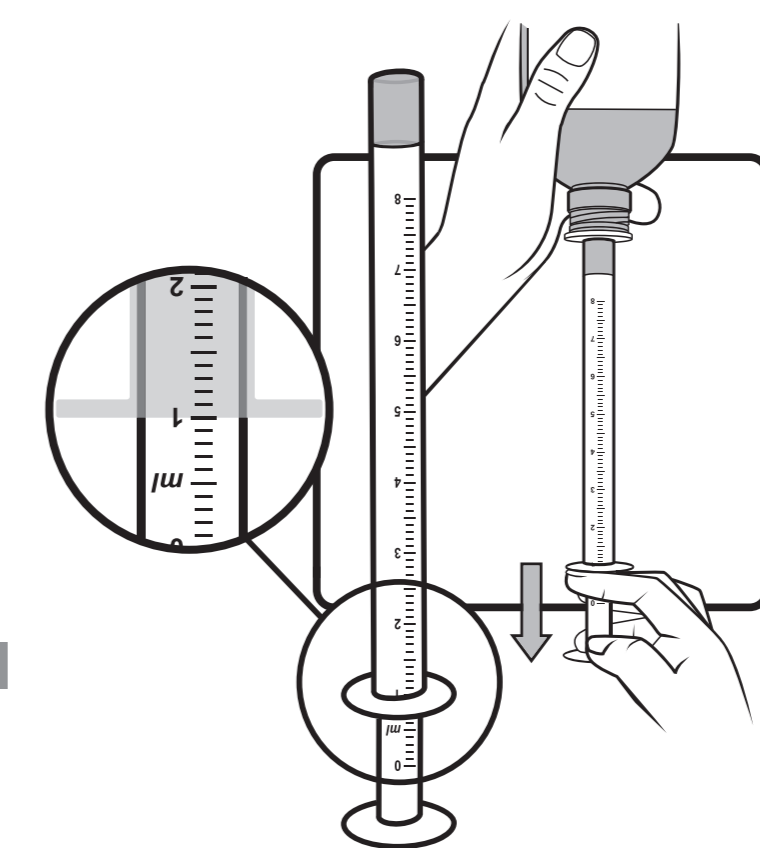
If there are large air bubbles in the oral syringe (as seen on the figure on the left) or if you have drawn up the wrong dose of AGAMREE, insert the syringe tip firmly into the bottle adapter while the bottle is in an upright position. Push the plunger all the way down so that AGAMREE flows back into the bottle and repeat Steps 4 through 6.



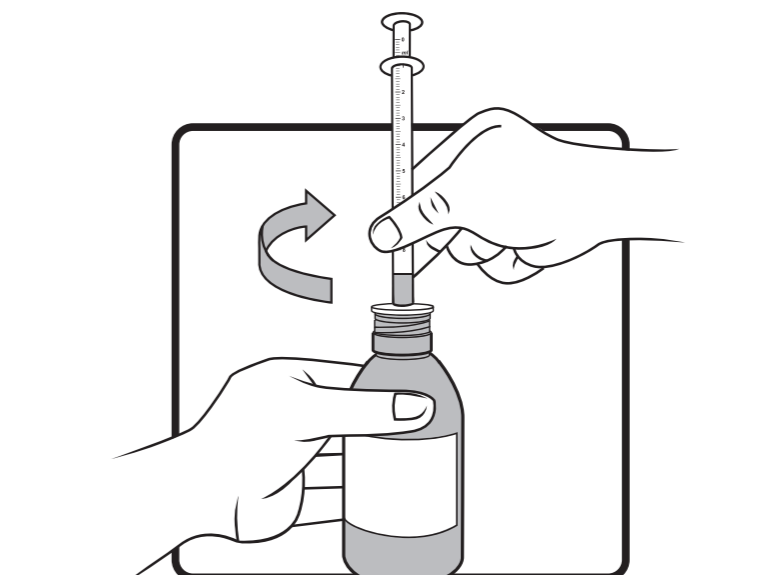
Step 2. Remove the child-resistant bottle cap by pushing it firmly down and turning it counter clockwise.



Step 6. Check your dose in millilitres (ml) as prescribed by your doctor. Find the gradation to read the dose in millilitres (ml) on the plunger as shown in the picture on the right. On the depicted scale, each line corresponds to 0.1 ml. In the example, a dose of 1 ml is shown. Do not take more than the prescribed daily dose.



Step 7. Turn the entire bottle right side up and remove the oral syringe carefully from the bottle.



Do not hold the oral syringe by the plunger, because the plunger may come out.

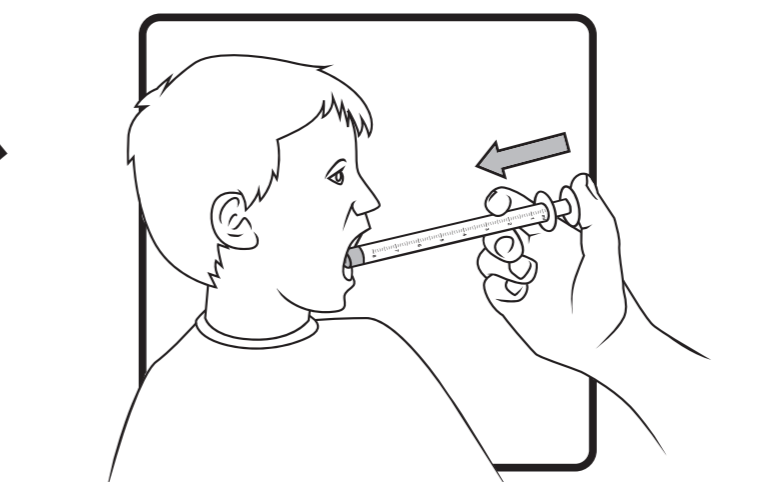
GIVING AGAMREE

Step 8. Do not mix the medicine with any liquid before giving.

The patient must sit upright when taking the medicine. Empty the syringe directly into the mouth.

Gently press the plunger to empty the syringe. Do not forcefully push on the plunger.

To avoid the risk of choking, do not squirt the medicine to the back of the mouth or throat.

**AFTER GIVING AGAMREE**

Step 9. Close the bottle with the child-resistant cap after each use.

Step 10. Disassemble the oral syringe, rinse under running cold water and air dry prior to next use.

Each oral syringe supplied with AGAMREE may be used for up to 45 days.

Enteral feeding tube

AGAMREE can be administered via an enteral feeding tube, following the instructions present in the enteral feeding tube kit. The usual prescribed dose of AGAMREE should be used, no dilution is required. Do not mix with the feeding

formula or other products. The tube must be flushed before and after administration of AGAMREE, using the syringe provided in the enteral feeding tube kit. A minimum of 20 ml of water should be used to flush the tube.

If you take more AGAMREE than you should

If you take too much AGAMREE, contact your doctor or a hospital for advice. Show the AGAMREE package and this leaflet. Medical treatment may be necessary.

If you forget to take AGAMREE

Do not take any more AGAMREE and do not repeat the dose. Take your next dose as normal. Talk to your health care professional if you are concerned.

If you stop taking AGAMREE

Take AGAMREE for as long as your doctor tells you to. Talk to your doctor before stopping AGAMREE treatment, as your dose needs to be gradually reduced to avoid undesirable side effects.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Treatment with AGAMREE leads to adrenal insufficiency. Talk to your doctor before starting AGAMREE (refer to Section 2 for more information).

The following side effects have been reported with AGAMREE at a very common frequency (may affect more than 1 in 10 people):

- More rounded, swollen aspect of the face (Cushingoid)
- Increase of body weight (weight increased)
- Increased appetite

Irritability**Vomiting**

The following side effects have been reported at a common frequency (may affect up to 1 in 10 people):

- Belly pain (abdominal pain)
- Pain in the upper belly (abdominal pain upper)
- Diarrhoea
- Headache

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store AGAMREE

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton and the bottle label after "EXP".

The expiry date refers to the last day of that month. This medicine does not require any special temperature storage conditions.

After your first open AGAMREE, store the bottle upright in a refrigerator (2 °C – 8 °C). The medicine can be kept in the refrigerator for up to 3 months.

Discard any unused medicine within 3 months after first opening the bottle.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What AGAMREE contains**

The active substance is vamorolone. Each ml of suspension contains 40 mg of vamorolone.

The other ingredients are: citric acid (monohydrate) (E 330), disodium phosphate (E 339), glycerol (E 422), orange flavour, purified water, sodium benzoate (E 211) (see section 2: "AGAMREE contains sodium benzoate"), sucralose (E 955), xanthan gum (E 415) and hydrochloric acid (for pH adjustment). See section 2 "AGAMREE contains sodium benzoate and sodium".

What AGAMREE looks like and contents of the pack

AGAMREE is a white to off-white oral suspension. It comes in an amber coloured glass bottle with a polypropylene tamper evident child-resistant closure with low density polyethylene liner. The bottle contains 100 ml of oral suspension. Each pack contains one bottle, a bottle adapter and two identical oral syringes for dosing. The oral syringes are graduated from 0 to 8 ml by increments of 0.1 ml.

Marketing Authorisation Holder and Manufacturer

Santhera Pharmaceuticals (Deutschland) GmbH
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