

LAVERDIA™-CA1 (verdinexor tablets)

Client Information Sheet

The client information sheet contains important information about **LAVERDIA-CA1 (verdinexor tablets)**. You should read this information before you start giving your dog LAVERDIA-CA1 and review it each time the prescription is refilled as there may be new information. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk with your veterinarian if you do not understand any of this information or if you want to know more about LAVERDIA-CA1.

LAVERDIA-CA1 is conditionally approved by the FDA. This means for this indication (i.e., the treatment of lymphoma), effectiveness has not been fully demonstrated; but the product has demonstrated a reasonable expectation that it is effective. This means that the product is reasonably expected to provide the intended effect when used under the conditions of use described in the labeling. An additional clinical trial will be conducted in dogs with lymphoma to determine effectiveness (how well the drug works). Conditionally approved animal drugs are limited to a specific use, in this case for lymphoma. Additional information on conditional approval can be found at www.fda.gov, search “animal conditional approval”.

What is LAVERDIA-CA1?

LAVERDIA-CA1 is a conditionally approved cancer drug used to treat lymphoma in dogs. The active ingredient in LAVERDIA-CA1 is verdinexor, a substance that works by preventing tumor suppressing proteins from leaving the nucleus of cells, resulting in disruption of cancer cell survival and eventual cancer cell death.

What do I need to tell my veterinarian before my dog is treated with LAVERDIA-CA1?

Tell your veterinarian:

- About other medications your pet is taking, including prescription drugs, over the counter drugs, heartworm preventatives, flea and tick medications, and vitamins and supplements, including herbal medications.
- About your dog’s previous or current medical conditions, including any infection.
- If your dog is pregnant, nursing puppies, or you intend to breed him/her.

How is my dog given LAVERDIA-CA1?

- See the **Handling Instructions** section (on the reverse side of this sheet) to learn more about safely administering LAVERDIA-CA1 to your dog.
- LAVERDIA-CA1 is given by oral administration (by mouth) to dogs.
- **Feed your dog a small meal immediately before giving LAVERDIA-CA1.**
- LAVERDIA-CA1 may be hidden inside a treat but be certain your dog swallows the entire tablet(s). It is not recommended that tablets be placed directly in a meal/food bowl as it may be difficult to determine if they have been eaten if the entire meal is not consumed by your dog.
- Follow your veterinarian’s instructions for how much and how often to give LAVERDIA-CA1. Your dog may need to take a combination of different tablet sizes to receive the correct dose of LAVERDIA-CA1. Give all tablets at the same time. Do not change this dose or regimen without consulting with your veterinarian.
- Give each dose of LAVERDIA-CA1 at least 72 hours apart (e.g., Monday and Thursday or Tuesday and Friday).
- If you miss a dose of LAVERDIA-CA1, do not make up the dose. Instead, simply give the next regularly scheduled dose. Be sure to inform your veterinarian of any missed doses or any difficulty with giving the tablets.

How will LAVERDIA-CA1 affect my dog’s cancer?

LAVERDIA-CA1 is intended to treat your dog’s cancer. Frequent check-ups by your veterinarian are necessary to determine whether your dog is responding to treatment, and to decide whether your dog should continue to receive LAVERDIA-CA1.

What are some possible side effects of LAVERDIA-CA1?

LAVERDIA-CA1 may cause side effects, even at the prescribed dose. Serious side effects can occur, with or without warning.

The most frequent side effects are:

- Decreased/Loss of appetite
- Weight loss
- Vomiting
- Diarrhea
- Lethargy

There are other side effects that may occur. For more information about side effects ask your veterinarian.

Stop LAVERDIA-CA1 immediately and contact your veterinarian if you notice any of the following changes in your dog:

- Refusal to eat for more than 1 day
- Repeated vomiting or diarrhea
- Lethargy
- If your dog experiences other changes that concern you

This client information sheet gives the most important information about LAVERDIA-CA1. For more information about LAVERDIA-CA1, talk to your veterinarian.

To report a suspected adverse reaction (side effect) call Anivive Lifesciences at 1-833-264-8483.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or at www.fda.gov/reportanimalae.

See reverse side for Handling Instructions

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Handling Instructions:

What do I need to know to handle LAVERDIA-CA1 (verdinexor tablets) safely?

Because LAVERDIA-CA1 is an anti-cancer drug, extra care must be taken when handling the tablets, giving the drug to your dog, and cleaning up after your dog.

- LAVERDIA-CA1 is not for use in humans.
- Do not eat, drink, or smoke while handling the product.
- Keep LAVERDIA-CA1 in a secure storage area:
 - Out of the reach of children. Children should not come in contact with LAVERDIA-CA1.
 - Out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.
- Do not store near food or near a food preparation area, or with medications intended for use in humans.
- Pregnant women, women who may become pregnant, and nursing women should not handle or administer LAVERDIA-CA1 or come in contact with the feces, urine, vomit, or saliva from LAVERDIA-CA1 treated dogs.
- LAVERDIA-CA1 may harm an unborn baby. For pregnant and nursing women, accidental ingestion of LAVERDIA-CA1 may have adverse effects on pregnancy or the nursing baby.
- LAVERDIA-CA1 may affect female and male fertility.

How to minimize exposure to the active ingredient when handling LAVERDIA-CA1?

The following handling procedures will help to minimize exposure to the active ingredient in LAVERDIA-CA1 for you and other members of your household:

- Anyone who administers LAVERDIA-CA1 to your dog should wear protective disposable chemotherapy resistant gloves (e.g. nitrile or latex gloves tested for use with chemotherapy drugs) when handling LAVERDIA-CA1. Check with your veterinarian to ensure you have the appropriate gloves.
- Minimize the number of people handling LAVERDIA-CA1.
- When you or others are handling the tablets:
 - Do not split or crush the tablets to avoid disrupting the protective film coating.
 - LAVERDIA-CA1 tablets should be administered to your dog immediately after they are removed from the bottle.
 - Protective disposable chemotherapy resistant gloves should be worn if handling broken or moistened tablets. If your dog spits out the LAVERDIA-CA1 tablet, the tablet will be moistened and should be handled with protective disposable chemotherapy resistant gloves.
 - If the LAVERDIA-CA1 tablet is “hidden” in a treat, make sure that your dog has eaten the entire dose. This will minimize the potential for exposure to children or other household members to LAVERDIA-CA1.
- Return any unused LAVERDIA-CA1 to your veterinarian.

What should I do in case of accidental contact when handling LAVERDIA-CA1?

- In case of contact with the skin, wash the affected area immediately and thoroughly with soap and water.

- In the case of accidental eye exposure:
 - Rinse the eyes with large amounts of tap water (use eyewash station if present) for 10 minutes while holding back the eyelid.
 - Remove contact lenses.
 - Seek medical advice immediately and show the package insert, label, or client information sheet to the physician.
- **If LAVERDIA-CA1 is accidentally ingested, or if there is significant contact with feces, urine, vomit, or saliva of dogs during treatment or within 3 days after the last treatment without proper precautions, seek medical advice immediately. It is important to show the treating physician a copy of the package insert, label, or client information sheet.**

How do I safely clean up after my dog during treatment with LAVERDIA-CA1?

Because LAVERDIA-CA1 is a cancer treatment drug, extra care must be taken when cleaning up after your dog for **3 days** after the last treatment with LAVERDIA-CA1.

- Avoid direct contact with feces, urine, vomit, or saliva during treatment and for **3 days** after the dog has completed treatment with LAVERDIA-CA1.
- Any skin that comes in contact with feces, urine, vomit, or saliva should be washed immediately with soap and water.
- When cleaning up feces, urine, vomit, or saliva you should wear protective disposable chemotherapy resistant gloves and collect the contaminated material with disposable absorptive material (such as paper towels) and place them into a plastic bag. Carefully remove the gloves and place them in the bag and tie or fasten it securely. Wash your hands thoroughly afterwards.
- You should not wash any items soiled with feces, urine, vomit, or saliva from your dog with other laundry during treatment and for **3 days** after the dog has completed treatment.
- Do not let your dog urinate or defecate in areas where people may come in direct contact with the urine or feces.
- Children should not come in contact with the feces, urine, vomit, or saliva of treated dogs.

Because LAVERDIA-CA1 may be present in your dog’s saliva during treatment and for **3 days** after the last treatment, wear protective disposable chemotherapy resistant gloves when handling the dog’s toys, food bowl, and water bowl. Wash food and water bowls separately from other items.

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