



CLIENT INFORMATION SHEET

TANOVEA™-CA1 (rabacfosadine for injection)

The Client Information Sheet contains important information about TANOVEA-CA1. You should read this information when your pet begins treatment with TANOVEA-CA1 and review it each time your pet receives treatment 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 TANOVEA-CA1.

TANOVEA-CA1 is conditionally approved by the FDA. This means the product has a reasonable expectation that it is effective. A clinical trial will be conducted to determine effectiveness (how well the drug works). Conditionally approved animal drugs are limited to a specific use which can be found on the package insert. Additional information on conditional approval can be found by searching <http://www.fda.gov> for "conditional approval."

Your veterinarian has decided to include TANOVEA-CA1 as a part of your dog's treatment plan for lymphoma. Be sure to speak with your veterinarian about all parts of your dog's treatment plan.

What is TANOVEA-CA1?

- TANOVEA-CA1 is an acyclic nucleotide phosphonate used to treat lymphoma, a form of cancer that affects dogs.
- The active ingredient in TANOVEA-CA1 is rabacfosadine, a substance that works by killing rapidly growing tumor cells.

What should I tell my veterinarian about my dog before he/she receives TANOVEA-CA1?

- Tell your veterinarian about all other medications your pet is taking, including: prescription drugs, over the counter drugs, heartworm preventatives, flea and tick medications, vitamins and supplements, including herbal medications.
- Tell your veterinarian about your pet's previous or current medical conditions.
- Tell your veterinarian if your dog is pregnant, nursing puppies, or is intended for breeding purposes.

How is TANOVEA-CA1 given to my dog?

- TANOVEA-CA1 may only be given by or under the supervision of a veterinarian.
- TANOVEA is given by injection into a vein over 30 minutes, once every three weeks, repeated up to five times.

How will TANOVEA-CA1 affect my dog?

- TANOVEA-CA1 is intended to treat your dog's lymphoma. As with other cancer treatments, it can be difficult to predict whether your dog's lymphoma will respond to TANOVEA-CA1, and if response is seen, how long your dog will remain responsive to TANOVEA-CA1.
- Regular check-ups by your veterinarian are necessary to determine whether your dog is responding as expected, and to decide whether your dog should continue to receive TANOVEA-CA1.

What are some possible side effects of TANOVEA-CA1?

- Like all drugs, TANOVEA-CA1 may cause side effects, even at the prescribed dose. Serious side effects can occur, with or without warning, and may in some situations result in death.

- The most common side effects that may occur with TANOVEA-CA1 include: decreased white blood cell count, diarrhea, vomiting, decreased/loss of appetite, weight loss, lethargy, and skin issues (hair loss, sores, scabs).
- Other side effects may occur. For more information about side effects ask your veterinarian.

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
- Fever
- Difficulty breathing
- Or if your dog experiences other changes that concern you

Because TANOVEA-CA1 is an anti-cancer drug, extra care must be taken when handling and cleaning up after your pet for 5 days after treatment.

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

- Cleaning up after your pet:
 - Avoid direct contact with urine, stool, vomit, and saliva for **5 days** after your dog is treated with TANOVEA-CA1.
 - When cleaning up urine, stool, vomit, or saliva you should wear 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 for general household disposal. Wash your hands thoroughly afterwards. Check with your veterinarian to ensure you have the appropriate gloves.
 - You should not wash any items soiled with urine, stool, vomit, or saliva from your dog with other laundry.
 - Do not let your dog urinate or defecate in areas where people may come in direct contact with the urine or stool.
- Because TANOVEA-CA1 may be present in the pet's saliva for **5 days** after treatment, take precautions in handling the dog's toys, food bowl, and water bowl. Wash food and water bowls separately from other items.

This client information sheet contains a summary of important information about TANOVEA-CA1. For more detailed information about TANOVEA-CA1, talk with your veterinarian.

To report a suspected adverse reaction (side effect) call 1-877-468-3832. For additional information about adverse drug experience reporting for animal drugs, contact the FDA at 1-888-FDA-VETS or online at <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

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