ProHeart® 6 (moxidectin)

Sustained Release Injectable for Dogs

For potential drug toxicity described in the sheet.

ProHeart 6 should be administered with caution in dogs with pre-existing allergic disease, including food allergy, atopy, and flea allergy dermatitis. In some cases, immediate. The Safety Data Sheet (SDS) contains more detailed occupational safety information.

Not for human use. Keep this and all drugs out of the reach of children.

CONTRAINDICATIONS

in the sheet. The Client Information Sheet is attached to this package insert and available

DOSAGE AND ADMINISTRATION

For initial mixing instructions). Once constituted,

Injection Technique:

CAUTION

moxidectin/ kg bodyweight (0.0773 mg/lb.). To ensure accurate dosing, calculate each dose based on the dog's weight at the time of treatment. Do not overdose growing weight loss. When replacing another heartworm preventive product, ProHeart 6 should be given within one month of the last dose of the former medication.

Precautions

for discussions with owners.

DOSAGE

www.proheart6.com/ for reprinting to provide to the owner.

Moxidectin is a semi-synthetic methoxime derivative of nemadectin which is a fermentation product of Streptomyces. Moxidectin is a pentacyclic 16-membered lactone macrolide.

PHARMACOLOGY

http://www.fda.gov/animalvets and review with owners before administering ProHeart 6. Owners should be advised of the potential for adverse reactions, including anaphylaxis, and be informed of the clinical signs associated with drug toxicity (see WARNINGS, PRECAUTIONS and ADVERSE REACTIONS sections) for discussion with owners.

If you have any questions or concerns about ProHeart 6, talk to your veterinarian.

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

What is ProHeart 6?

ProHeart 6 is a sustained-release injectable product that prevents heartworm disease in dogs 6 months of age and older. ProHeart 6 is given by your veterinarian. Some ProHeart 6 clients report adverse reactions. For more information, talk to your veterinarian.

What is ProHeart 6 side effects could happen to my dog?

It is important to contact your veterinarian if you observe any signs of illness in your dog. Severe reactions require emergency treatment by your veterinarian. Match your dog for the following possible signs of illness:

- Allergic reaction – The most common side effects of ProHeart 6 are allergic reactions, including swelling of the face, tongue and mouth. Severe reactions may cause death.

- Suspension microspheres should be resuspended before each use.
There were no reports of injection site reactions in these field studies and evaluations of the injection sites revealed no abnormalities.

Injection site observations were recorded during effectiveness and safety studies. In clinical studies, ProHeart 6 was administered at six-month intervals to client-owned dogs under field conditions. Injection site reactions were observed in dogs treated with ProHeart 6: anaphylaxis, vomiting, diarrhea (with and without blood), listlessness, depression, lethargy, anorexia, fever, weight loss, weakness, and ataxia.

In some cases, death has been reported as an outcome of the adverse events listed above. Cardiopulmonary signs such as coughing and dyspnea may occur in heartworm positive dogs treated with ProHeart 6.

Hepatic: leukocytosis, anemia, thrombocytopenia
Respiratory: dyspnea, tachypnea, coughing
Neurological: seizures, ataxia, trembling, hind limb paresis
Dermatological: depression, lethargy, anorexia, fever, weight loss, weakness
Gastrointestinal: gastrointestinal, dermatologic, and hematologic

Some dogs treated with ProHeart 6 in laboratory effectiveness studies developed transient, localized inflammatory injection site reactions. These injection site reactions were visible grossly for up to 3 weeks after injection. Histologically, well-defined granulomas were observed in some dogs at approximately 5 months after injection. In field studies, the following adverse reactions were observed in dogs treated with ProHeart 6: anaphylaxis, vomiting, diarrhea (with and without blood), listlessness, depression, lethargy, anorexia, fever, weight loss, weakness, and ataxia.

In laboratory safety studies, ProHeart 6 was administered at 1, 3 and 5 times the recommended dose to 7-8 month old puppies. Injection sites were clipped to facilitate observation of the reactions. Injection site observations were recorded during testing. A third dog who was underweight for its age and breed and who had a history of congenital problems and was found to be heartworm positive in a routine medical examination died within a month of the second 6 month injection. A third dog who was underweight for its age and breed and who had a history of congenital problems and was found to be heartworm positive in a routine medical examination died within a month of the second 6 month injection. A third dog who was underweight for its age and breed and who had a history of congenital problems and was found to be heartworm positive in a routine medical examination died within a month of the second 6 month injection.

Hepatic: leukocytosis, anemia, thrombocytopenia
Respiratory: dyspnea, tachypnea, coughing
Neurological: seizures, ataxia, trembling, hind limb paresis
Dermatological: depression, lethargy, anorexia, fever, weight loss, weakness
Gastrointestinal: gastrointestinal, dermatologic, and hematologic

In laboratory safety studies, ProHeart 6 was administered at 1, 3 and 5 times the recommended dose to 7-8 month old puppies. Injection sites were clipped to facilitate observation of the reactions. Injection site observations were recorded during testing. In a laboratory safety study, ProHeart 6 was administered at 1, 3 and 5 times the recommended dose to 7-8 month old puppies. Injection sites were clipped to facilitate observation of the reactions. Injection site observations were recorded during testing. In a laboratory safety study, ProHeart 6 was administered at 1, 3 and 5 times the recommended dose to 7-8 month old puppies. Injection sites were clipped to facilitate observation of the reactions. Injection site observations were recorded during testing.

In some cases, death has been reported as an outcome of the adverse events listed above. Cardiopulmonary signs such as coughing and dyspnea may occur in heartworm positive dogs treated with ProHeart 6.

Hepatic: leukocytosis, anemia, thrombocytopenia
Respiratory: dyspnea, tachypnea, coughing
Neurological: seizures, ataxia, trembling, hind limb paresis
Dermatological: depression, lethargy, anorexia, fever, weight loss, weakness
Gastrointestinal: gastrointestinal, dermatologic, and hematologic

Some dogs treated with ProHeart 6 in laboratory effectiveness studies developed transient, localized inflammatory injection site reactions. These injection site reactions were visible grossly for up to 3 weeks after injection. Histologically, well-defined granulomas were observed in some dogs at approximately 5 months after injection. Some dogs treated with ProHeart 6 in laboratory effectiveness studies developed transient, localized inflammatory injection site reactions. These injection site reactions were visible grossly for up to 3 weeks after injection. Histologically, well-defined granulomas were observed in some dogs at approximately 5 months after injection. Some dogs treated with ProHeart 6 in laboratory effectiveness studies developed transient, localized inflammatory injection site reactions. These injection site reactions were visible grossly for up to 3 weeks after injection. Histologically, well-defined granulomas were observed in some dogs at approximately 5 months after injection.

In a laboratory safety study, ProHeart 6 was administered at 1, 3 and 5 times the recommended dose to 7-8 month old puppies. Injection sites were clipped to facilitate observation of the reactions. Injection site observations were recorded during testing. In a laboratory safety study, ProHeart 6 was administered at 1, 3 and 5 times the recommended dose to 7-8 month old puppies. Injection sites were clipped to facilitate observation of the reactions. Injection site observations were recorded during testing. In a laboratory safety study, ProHeart 6 was administered at 1, 3 and 5 times the recommended dose to 7-8 month old puppies. Injection sites were clipped to facilitate observation of the reactions. Injection site observations were recorded during testing. In a laboratory safety study, ProHeart 6 was administered at 1, 3 and 5 times the recommended dose to 7-8 month old puppies. Injection sites were clipped to facilitate observation of the reactions. Injection site observations were recorded during testing.

In some cases, death has been reported as an outcome of the adverse events listed above. Cardiopulmonary signs such as coughing and dyspnea may occur in heartworm positive dogs treated with ProHeart 6.

Hepatic: leukocytosis, anemia, thrombocytopenia
Respiratory: dyspnea, tachypnea, coughing
Neurological: seizures, ataxia, trembling, hind limb paresis
Dermatological: depression, lethargy, anorexia, fever, weight loss, weakness
Gastrointestinal: gastrointestinal, dermatologic, and hematologic

General: Pyrexia, lethargy, anemia, fever, weight loss, weakness
Neurological: Pyrexia, lethargy, anemia, fever, weight loss, weakness
Dermatological: Pyrexia, lethargy, anemia, fever, weight loss, weakness
Gastrointestinal: Pyrexia, lethargy, anemia, fever, weight loss, weakness

In some cases, death has been reported as an outcome of the adverse events listed above. Cardiopulmonary signs such as coughing and dyspnea may occur in heartworm positive dogs treated with ProHeart 6.

Hepatic: leukocytosis, anemia, thrombocytopenia
Respiratory: dyspnea, tachypnea, coughing
Neurological: seizures, ataxia, trembling, hind limb paresis
Dermatological: depression, lethargy, anorexia, fever, weight loss, weakness
Gastrointestinal: gastrointestinal, dermatologic, and hematologic

In some cases, death has been reported as an outcome of the adverse events listed above. Cardiopulmonary signs such as coughing and dyspnea may occur in heartworm positive dogs treated with ProHeart 6.

Hepatic: leukocytosis, anemia, thrombocytopenia
Respiratory: dyspnea, tachypnea, coughing
Neurological: seizures, ataxia, trembling, hind limb paresis
Dermatological: depression, lethargy, anorexia, fever, weight loss, weakness
Gastrointestinal: gastrointestinal, dermatologic, and hematologic

In some cases, death has been reported as an outcome of the adverse events listed above. Cardiopulmonary signs such as coughing and dyspnea may occur in heartworm positive dogs treated with ProHeart 6.

Hepatic: leukocytosis, anemia, thrombocytopenia
Respiratory: dyspnea, tachypnea, coughing
Neurological: seizures, ataxia, trembling, hind limb paresis
Dermatological: depression, lethargy, anorexia, fever, weight loss, weakness
Gastrointestinal: gastrointestinal, dermatologic, and hematologic

In some cases, death has been reported as an outcome of the adverse events listed above. Cardiopulmonary signs such as coughing and dyspnea may occur in heartworm positive dogs treated with ProHeart 6.

Hepatic: leukocytosis, anemia, thrombocytopenia
Respiratory: dyspnea, tachypnea, coughing
Neurological: seizures, ataxia, trembling, hind limb paresis
Dermatological: depression, lethargy, anorexia, fever, weight loss, weakness
Gastrointestinal: gastrointestinal, dermatologic, and hematologic

In some cases, death has been reported as an outcome of the adverse events listed above. Cardiopulmonary signs such as coughing and dyspnea may occur in heartworm positive dogs treated with ProHeart 6.