

SolutionKits™ – Pimobendan_{Rx}

Compounding Kit

Pimobendan 2.5 mg/mL Oral Suspension

FOR VETERINARY COMPOUNDING ONLY

NOT FOR HUMAN USE – RX ONLY

NOT FOR CONSUMER SALE OR USE

DESCRIPTION

Each SolutionKits™ – Pimobendan Compounding Kit contains: (i) 1.1 g of Pimobendan powder USP; (ii) 440 mL of oral suspension vehicle, and (iii) 1 Plastic Funnel for Compounding. Using the kit and following the directions provided results in an oral suspension of 440mL containing 2.5mg/mL of Pimobendan oral solution.

Content

NDC	46144-606-01
Size	440 mL
Pimobendan Powder USP	1.1 g
Liquid Suspension Base	440 mL
Plastic Funnel	1

Compounding Directions

Contents and Safety. Each SolutionKits™ – Pimobendan Compounding Kit contains the specified quantities of Pimobendan powder USP, liquid suspension vehicle. **Review these directions carefully prior to use to ensure a uniform, homogeneous finished product.** Review enclosed Package Insert and take all appropriate handling and safety precautions.

TO THE COMPOUNDING PRACTITIONER:

1. Loosen the Pimobendan Powder:

- 1.1. Do **not** shake – the bottle containing the Pimobendan (the “POWDER Container”).
- 1.2. Hold the POWDER container upright, and firmly tap the bottom and bottom-side edges against a hard surface to loosen the powder.
- 1.3. Remove the plastic cap of the POWDER container.
- 1.4. Tap the top of the seal liner to dislodge any powder that may have adhered to the inside of the seal.
- 1.5. Carefully and slowly peel back the inner seal liner.
- 1.6. Place the Supplied plastic funnel in the opening of the POWDER container.

2. Agitate the Suspension. Shake the liquid suspension vehicle (“Suspension”) bottle for at least 5 seconds.

3. Add **HALF** of the Suspension vehicle to the POWDER Container.

- 3.1. Do **Not** attempt to add the Pimobendan powder to the Suspension vehicle.
- 3.2. Open the Suspension vehicle container and pour approximately half the Suspension vehicle into the POWDER Container.

4. Agitate the Partial Mixture. **This step is very important for product quality.** Remove the supplied Plastic Funnel, securely replace the POWDER Container cap, and shake well for approximately 60 seconds.

5. Add Remaining Suspension. Replace the supplied plastic funnel in the opening of the POWDER Container and Empty the remaining Suspension Vehicle into the Powder Container, and allow the remaining Suspension vehicle to drain into the Powder Container for at least 10 seconds. Discard the Suspension vehicle container.



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6. Agitate the Completed Compound. Replace the POWDER Container cap and shake well **for (another) 60 seconds.**

7. Record Compounding Date: Record the date product was compounded in your records—and in the space indicated on the POWDER Container. Compounded Product BUD 180 days after compounding.

8. Dispense. Dispense the Pimobendan oral solution to the client and include adequate instructions. If dispensing less than the full quantity compounded, decant into in separate prescription bottle, affix an appropriate dispensing label, and include adequate written instructions for the client.

9. **Important Instructions (for Client).** Shake the compounded Pimobendan oral suspension well (for approximately 60 seconds) **before each use. This step is very important for ensuring accurate dosing.** Educate the client on the importance of this step, and include in your written dispensing instructions to the client.

WARNINGS

Not for use in Animals hypersensitive to Pimobendan or any condition where increased Cardiac output is inappropriate.

Do not use in Animals that are breeding, pregnant, or lactating unless the benefits outweigh the risks.

Pimobendan Side effects can include but not limited to loss of appetite, lethargy, diarrhea, dyspnea, azotemia, and ataxia. Less common side effects include change in kidney function, weakness and balance issues, fluid accumulation in the lungs or abdomen, cough, and changes in heart rhythm.

You can see a decrease in the effects of Pimobendan in Companion animals using Calcium channel blockers and certain beta blockers.

Pimobendan should be used with Caution in animals using calcium antagonists (verapamil and diltiazem) and beta-antagonists (propranolol, atenolol).

Pimobendan should not be used to treat hypertrophic cardiomyopathy, aortic stenosis, or any condition where increased cardiac output is inappropriate.

Avoid use in animals with uncontrolled abnormal heart rhythms, known congenital heart defects, diabetes, or other metabolic disorders.

Compounded SolutionKits™ – Suspension vehicle meets USP <51> Antimicrobial Effectiveness Testing.***

Prior to compounding, store SolutionKits™ – Pimobendan Compounding Kit at room temperature 15° – 30° C (59° – 86° F). Store the final compounded formulation at room temperature 15° – 30° C (59° – 86° F).

For oral use only. Avoid contact with eyes. Keep container tightly closed. Keep out of the reach of children and pets. Protect from light. Protect from freezing. When stored at under listed conditions the beyond-use date of the compounded product is **no later than 180 days.**

How Supplied

SolutionKits™ – Pimobendan Compounding Kit is available as follows: 440 mL as dispensed (46144-606-01)

* Certificate of analysis on file

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*** Data and documentation on file

Distributed by:

A.P.I. Solutions, Inc.

Daphne, AL 36526

For Questions or Comments

Please Call 855-878-1489

Rx Only

