SolutionKits[™]– Doxycycline

Compounding Kit

Doxycycline 50 mg/mL Oral Suspension

FOR VETERINARY COMPOUNDING ONLY NOT FOR HUMAN USE – RX ONLY NOT FOR CONSUMER SALE OR USE

DESCRIPTION

Each SolutionKits[™] – Doxycycline Compounding Kit contains: (i) 34.27 g of doxycycline hyclate 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 460mL containing 50 mg/mL of Doxycycline oral solution.

Contents

NDC	46144-604-01
Size	460 mL
Doxycycline Hyclate Powder USP	34.27 g
Liquid Suspension Base	440 mL
Plastic Funnel	1



1-1-21

Compounding Directions

Contents and Safety. Each SolutionKitsTM – Doxycycline Compounding Kit contains the specified quantities of doxycycline 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.



- 1.1. Do **not** shake the bottle containing the
- Doxycycline (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.
- Remove the plastic cap of the POWDER container.
 Tap the top of the seal liner to dislodge any powder that request here a the basel due to be included.
- 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. <u>Agitate the Suspension</u>. Shake the liquid suspension vehicle ("Suspension") bottle for at least 5 seconds.
- Add HALF of the Suspension vehicle to the POWDER Container.
 3.1. Do Not attempt to add the doxycycline powder to the Suspension vehicle.
 - 3.2. Open the Suspension vehicle container and pour approximately half the Suspension vehicle into the POWDER Container.
- 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. <u>Add Remaining Suspension</u>. 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.
- Agitate the Completed Compound. Replace the POWDER Container cap and shake well for (another) 60 seconds.
- <u>Record Compounding Date</u>: 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.
- <u>Dispense</u>. Dispense the doxycycline oral solution to the client and include adequate instructions. If dispensing less than the full quantity compounded, decant into separate prescription bottle, affix an appropriate dispensing label, and include adequate written instructions for the client.
- Important Instructions (for Client). Shake the compounded doxycycline 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

Do not Use in animals that may enter the Food Chain.

Do not use in Animals that are breeding, pregnant, or lactating because of risk of skeletal limb abnormalities and discolorations of teeth. It should be avoided unless the benefits outweigh the potential risks.

Doxycycline and other Tetracycline antibiotics are generally not used with bacterial antibiotics such as penicillin, cephalosporin, and aminoglycosides.

Do not administer within two (2) hours of any antacid.

Oral Iron also interferes with absorption of doxycycline and should be separated by three (3) hours.

Most common side effects in dogs and cats are GI upset including Nausea and vomiting Compounded SolutionKits[™]– Suspension vehicle meets USP<51> Antimicrobial Effectiveness Testing^{***}

Prior to Compounding, store SolutionKits[™] Doxycycline Compounding Kit at room temperature 15-30 °C (59-86 °F) Store the final compounded formulation under room temperature15-30 °C (59-86 °F).

For Oral use only. Avoid contact with eyes. Keep container tightly closed. Keep pout of reach of children and pets. Protect from freezing. When stored at under listed conditions the beyond-use-date of the compound is **NO LATER THAN 180 DAYS.**

How Supplied

SolutionKits[™]– Doxycycline Compounding Kit is available as follows: 460 mL as dispensed (46144-604-01)

* Certificate of analysis on file

- ** Certificate of analysis on file
- *** Data and documentation on file



<u>Distributed by</u>: A.P.I. Solutions, Inc. Daphne, AL 36526 For Questions or Comments Please Call 855-878-1489

Rx Only