

SolutionKits™ – Metronidazole

Compounding Kit
Metronidazole 50 mg/mL Oral Suspension

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

DESCRIPTION

Each SolutionKits™ – Metronidazole Compounding Kit contains: (i) 36.9 g of metronidazole benzoate powder USP (equivalent to 23.1g of Metronidazole); (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 metronidazole.

Contents

NDC	46144-602-01
Size	460 mL
Metronidazole Benzoate USP	36.9 g
Liquid Suspension Base	440 mL
Plastic Funnel	1

Compounding Directions

Contents and Safety. Each SolutionKits™ – Metronidazole Compounding Kit contains the specified quantities of metronidazole benzoate powder USP (for convenience, sometimes “metronidazole benzoate”) and 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:

- Loosen the Metronidazole Benzoate Powder:**
 - Do **not** shake the bottle containing the metronidazole benzoate powder (the “POWDER Container”).
 - Hold the POWDER container upright, and firmly tap the bottom and bottom-side edges against a hard surface to loosen the powder.
 - Remove the plastic cap of the POWDER container.
 - Tap the top of the seal liner to dislodge any powder that may have adhered to the inside of the seal.
 - Carefully and slowly peel back the inner seal liner.
 - Place the Supplied plastic funnel in the opening of the POWDER container.
- Agitate the Suspension.** Shake the liquid suspension vehicle (“Suspension”) bottle for at least 5 seconds.
- Add HALF of the Suspension vehicle to the POWDER Container.**
 - Do **Not** attempt to add the Metronidazole Benzoate Powder to the Suspension vehicle.
 - 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.
- 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.
- Agitate the Completed Compound.** Replace the POWDER Container cap and shake well **for (another) 60 seconds.**
- 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.
- Dispense.** Dispense the metronidazole 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.
- Important Instructions (for Client).** Shake the compounded metronidazole 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.

Avoid use in animals that are breeding, pregnant (especially in the first trimester), or lactating unless the benefits outweigh the risks. Metronidazole is excreted in breast milk and has been shown to cause birth defects in laboratory animals.

Use with caution in conjunction with anticoagulant therapies, especially warfarin and coumarin anticoagulants.

Use with caution in juvenile animals and animals with liver disease or decreased renal function: dosage may require adjustment. Animals with liver problems may be more at risk for side effects and (if used at all) usually require lower dosages.

Drug interactions may occur between metronidazole and drugs such as alcohol, oral anticoagulant drugs (blood thinners), cimetidine, phenobarbital and phenytoin.

The most common side effects in dogs and cats relate to digestive the tract and include: (i) excessive salivation, gagging, regurgitation, and/or pawing at the mouth from the medication’s taste, and/or (ii) more generally, nausea, vomiting, and decreased appetite. Horses may refuse to eat feed that has been mixed with metronidazole.

Less common, rare, and/or potentially serious side effects in dogs and cats include: vomiting (other than immediate regurgitation after administration), anorexia (especially sustained refusal to eat), diarrhea, weakness, low white blood cell count, liver failure, blood in the urine, dark urine, and neurological signs (including depression, lethargy, ataxia, disorientation, head tilt, tremors, bradycardia, rigidity, stiffness, and seizures). Serious and/or neurologic side effects (i) are associated with accidental overdose but also sustained moderate-to-high-dose therapy, (ii) may appear as late as 7-12 days following the start of treatment, and (iii) may persist for several days (or even weeks) after discontinuation.

Very rarely metronidazole may cause cutaneous vasculitis. Discontinue and/or reevaluate immediately if animal shows signs scaling, hair loss, bruising, swelling, and bumps on the skin.

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

Prior to compounding, store SolutionKits™ – Metronidazole Compounding Kit at room temperature 15° – 30° C (59° – 86° F). Store the final compounded formulation under 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™ – Metronidazole Compounding Kit is available as follows: 460 mL as dispensed (46144-602-01)

* Certificate of analysis on file
** Certificate of analysis on file
*** 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

