

SolutionKits™ – Gabapentin R_x

Compounding Kit
Gabapentin 50 mg/mL Oral Suspension

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

DESCRIPTION

Each SolutionKits™ – Gabapentin Compounding Kit contains: (i) 22.5 g of Gabapentin 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 450mL containing 50 mg/mL of Gabapentin oral solution.

Contents

NDC	46144-600-01
Size	450 mL
Gabapentin Powder USP	22.5 g
Liquid Suspension Base	440 mL
Plastic Funnel	1

Compounding Directions

Contents and Safety. Each SolutionKits™ – Gabapentin Compounding Kit contains the specified quantities of Gabapentin 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 Gabapentin Powder.

- 1.1. Do **not** shake – the bottle containing the Gabapentin (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 Gabapentin 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 Gabapentin 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 Gabapentin 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 gabapentin or anti-inflammatory drugs.

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

Use with extreme caution in animals with kidney disease or decreased renal function: dosage may require adjustment.

Use with caution in animals that are juvenile, smaller than 8 pounds, diabetic, or being treated with narcotic pain relievers, or that have heart disease or decreased liver function.

Do not suddenly discontinue the use of gabapentin, as potentially serious or even fatal seizures can occur, especially after long-term use.

Do not administer within 2 hours before or after administering any antacid.

Most common side effects include lethargy/somnolence, ataxia, and occasional diarrhea. Other side effects include decreased appetite, swelling of the limbs, and vomiting.

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

Prior to compounding, store SolutionKits™ – Gabapentin 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™ – Gabapentin Compounding Kit is available as follows: 450 mL as dispensed (46144-600-01)

* 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