FIRST®-Metronidazole 50 Rx

Metronidazole 50 mg/mL in FIRST® - Grape II Suspension Compounding Kit

FOR PRESCRIPTION COMPOUNDING ONLY

WARNING

Metronidazole has been shown to be carcinogenic in mice and rats. Unnecessary use of the drug should be avoided. See PRECAUTIONS and usage described in approved labeling for metronidazole containing products for additional information.

DESCRIPTION

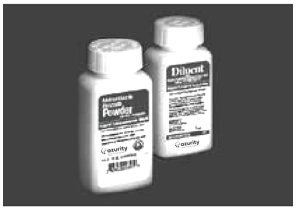
Each FIRST® - Metronidazole 50 Compounding Kit (5 FL OZ) is comprised of 12 g of metronidazole benzoate powder USP (equivalent to 7.5 g metronidazole) and 141 mL of Diluent (FIRST® - Grape II Suspension) containing ammonium glycyrrhizate, carboxymethylcellulose sodium, citric acid (anhydrous), grape flavor, microcrystalline cellulose, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate (dihydrate), sucralose, and xanthan gum.* When compounded, the final product provides a homogeneous suspension containing 50 mg per mL FIRST®-Metronidazole Oral Suspension. **

How Supplied and Compounding Directions

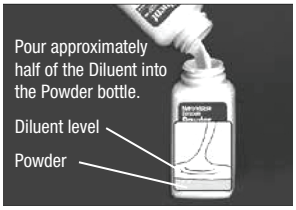
Size	5 FL OZ
NDC#	65628-202-05
Metronidazole Benzoate Powder	12 g
Diluent (FIRST®- Grape II Suspension)	141 mL

TO THE PHARMACIST

***Everything you need to make this* Rx included...**



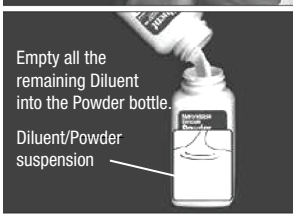
1. FIRST®- Metronidazole 50 Compounding Kit contains pre-measured metronidazole benzoate powder and Diluent (FIRST®- Grape II Suspension).



2. Important - Hold the neck of the bottle containing metronidazole benzoate powder and tap the bottom edges on a hard surface to loosen the powder. Remove the cap from the bottle. Tap the top of the induction seal liner to loosen any powder which may have adhered to the liner. Carefully and slowly peel back the inner foil seal liner from the bottle.

3. Shake the Diluent bottle for a few seconds. Open the suspension bottle and pour approximately half of the Diluent into ***the metronidazole benzoate powder bottle.***

4. ***Important:*** Replace the cap and shake the metronidazole benzoate powder bottle ***Well for approximately 60 seconds*** to ensure a well-mixed suspension.



5. Empty the remaining Diluent ***into the metronidazole benzoate powder bottle, and allow the remaining Diluent to drain into the powder bottle for 10 seconds.***

6. Replace the cap and shake the metronidazole benzoate powder bottle ***Well again for approximately 60 seconds.***

7. Dispense the metronidazole benzoate oral suspension in the bar coded bottle to the patient.

8. ***Important:*** Be sure to instruct your patient to wait for at least one hour before administering the first dose and also to ***shake the suspension Well*** before each use in order to ensure a well- mixed suspension.

WARNINGS

Central and Peripheral Nervous System Effects

Encephalopathy and peripheral neuropathy: Cases of encephalopathy and peripheral neuropathy (including optic neuropathy) have been reported with metronidazole.

Encephalopathy has been reported in association with cerebellar toxicity characterized by ataxia, dizziness, and dysarthria. CNS lesions seen on MRI have been described in reports of encephalopathy. CNS symptoms are generally reversible within days to weeks upon discontinuation of metronidazole. CNS lesions seen on MRI have also been described as reversible.

Peripheral neuropathy, mainly of sensory type has been reported and is characterized by numbness or paresthesia of an extremity.

Convulsive seizures have been reported in patients treated with metronidazole.

Aseptic meningitis: Cases of aseptic meningitis have been reported with metronidazole. Symptoms can occur within hours of dose administration and generally resolve after therapy is discontinued.

The appearance of abnormal neurologic signs and symptoms demands prompt evaluation of the benefit/risk ratio of the continuation of therapy (see Adverse Reactions in approved labeling for metronidazole containing products).

Compounded FIRST®-Metronidazole Suspension meets USP <51>, Antimicrobial Effectiveness Testing.***

Prior to compounding, store FIRST® - Metronidazole 50 Compounding Kit at room temperature 15º – 30ºC (59º – 86ºF). Store the final compounded formulation at room temperature 15º – 30ºC (59º – 86ºF) for up to 30 days. ***

For oral use only. Avoid contact with eyes. Keep container tightly closed. Keep out of the reach of children. Protect from light. Protect from freezing. When stored at room temperature the beyond-use date of the compounded product is ***no later than 30 days.***

How Supplied

FIRST®- Metronidazole 50 Compounding Kit is available as follows:
5 FL OZ (150 mL) as dispensed (65628-202-05)

* Certificate of analysis on file
** Equivalent to USP Metronidazole Benzoate Compounded Oral Suspension
*** Data and documentation on file

Rx ONLY
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Manufactured for:
azurity™ pharmaceuticals
Wilmington, MA 01887 USA
www.azurity.com

Grape Flavor

ORAL SUSPENSION ®

REV 02