FIRST®- Metronidazole 50 ℞

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

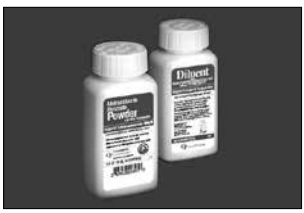
Each FIRST® - Metronidazole 50 Compounding Kit (5 FL OZ) is comprised of 12 g of metronidazole benzoate powder USP (equivalent to 7.5 g metronidazole) and 141 mL of Diluent (FIRST® - Grape II Suspension) containing artificial grape flavor, Avicel® RC591, citric acid (anhydrous), Magnasweet®100 (ammonium glycyrrhizate), purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate (dihydrate), sucralose, xanthan gum.* When compounded, the final product provides a homogeneous suspension containing 50 mg per mL of metronidazole in FIRST® - Grape II Suspension comparable to the active ingredient contained in Metronidazole Benzoate Oral Suspension.**

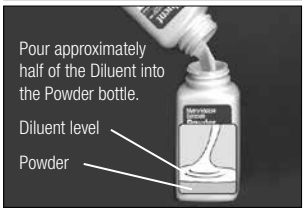
How Supplied and Compounding Directions

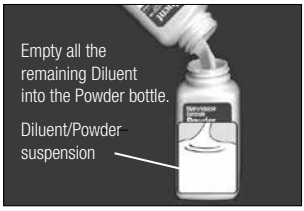
Size	5 FL OZ
NDC#	65628-202-05
Metronidazole Benzoate Powder	12 g
Diluent (FIRST®- Grape II Suspension)	141 mL

TO THE PHARMACIST

Everything you need to make this ℞ is 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 ***VIGOROUSLY for approximately 60 seconds*** to ensure a well-mixed suspension. Continue with the preparation.
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 ***VIGOROUSLY again for approximately 60 seconds.***
7. ***Important:*** 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 VIGOROUSLY 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).

FIRST® - Metronidazole 50 Compounding Kit components have a two-year expiration.** Prior to compounding, store FIRST® - Metronidazole 50 Compounding Kit at room temperature 15º – 30ºC (59º – 86ºF). Based on real time temperature and humidity testing, *compounded* FIRST® - Metronidazole 50 product is stable for at least 30 days at room temperature 15º – 30ºC (59º – 86ºF) [see USP].** Store the final compounded formulation at room temperature 15º – 30ºC (59º – 86ºF).

FIRST® - Grape II Suspension meets the requirements for a) total aerobic microbial count of not more than 100 cfu/mL, b) for total yeasts and molds of not more than 10 cfu per mL, and c) for the absence of the specified microorganisms *Escherichia coli* and *Pseudomonas aeruginosa* when tested as described in the current USP under <61> Microbial Enumeration Tests and <62> Tests for Specified Microorganisms. FIRST® - Grape II Suspension also meets the requirements as described in the current USP under <51> Antimicrobial Effectiveness Testing for Category 3 products.

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. The beyond-use date of the compounded product, as dispensed, when stored at room temperature 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)

FIRST® - Metronidazole 100 Compounding Kit is available as follows:
5 FL OZ (150 mL) as dispensed (65628-203-05)

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

℞ only

Issued: September 2016
U.S. Patent Pending

Manufactured for:

CUTISPHARMA®
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Grape Flavor

ORAL SUSPENSION®

REV. 0