FIRST®-Baclofen 5 ℞

Baclofen 5 mg/mL in FIRST®-Grape II Suspension Compounding Kit

FOR PRESCRIPTION COMPOUNDING ONLY

DESCRIPTION

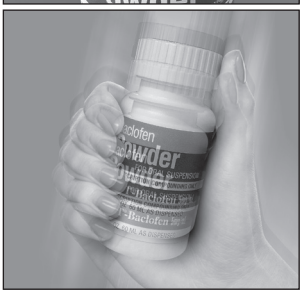
Each FIRST®- Baclofen 5 Compounding Kit is comprised of baclofen powder USP and Diluent (FIRST®- Grape II Suspension) containing artificial grape flavor, Avicel® RC591, citric acid (anhydrous), Magnasweet®100 (ammonium glycyrrhizate), purified water, saccharin sodium, simethicone emulsion, sodium benzoate,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

How Supplied and Compounding Directions

Size	4 FL OZ	2 FL OZ
NDC#	65628-101-04	65628-101-02
Baclofen Powder	0.6 g	0.3 g
Diluent (FIRST®- Grape II Suspension)	120 mL	60 mL

TO THE PHARMACIST

Everything you need to make this prescription is included...



1. FIRST®- Baclofen 5 Compounding Kit contains pre-measured baclofen powder and Diluent.

2. Important - Hold the neck of the bottle containing baclofen 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 for a few seconds. Open the Diluent bottle and empty about half of the Diluent ***into the baclofen powder bottle.*** Replace the cap and shake the baclofen powder bottle vigorously for approximately 60 seconds.

4. Empty the remaining Diluent ***into the baclofen powder bottle and allow Diluent to drain for 10 seconds.*** Replace the cap and shake the baclofen powder bottle vigorously for approximately 60 seconds.

5. Dispense the Baclofen oral suspension in the bar coded powder bottle to the patient.

6. Instruct patient to shake the bottle vigorously before each use.

WARNINGS

1. Abrupt Drug Withdrawal: Hallucinations and seizures have occurred on abrupt withdrawal of baclofen. Therefore, except for serious adverse reactions, the dose should be reduced slowly when the drug is discontinued

2. Impaired Renal Function: Because baclofen is primarily excreted unchanged through the kidneys, it should be given with caution, and it may be necessary to reduce dosage.

3. Pregnancy: Baclofen has been shown to increase the incidence of omphaloceles (ventral hernias) in fetuses of rats approximately 13 times the maximum dose recommended for human use, at a dose which caused significant reductions in food intake and weight gain in dams. This abnormality was not seen in mice or rabbits.

There was also increased incidence of incomplete sternebral ossification in fetuses of rats given approximately 13 times the maximum recommended human dose, and an increase incidence of unossified phalangeal nuclei of forelimbs and hindlimbs in fetuses of rabbits given approximately 7 times the maximum recommended human dose. In mice, no teratogenic effects were observed, although reductions in mean fetal weight with consequent delays in skeletal ossification were present when dams were given 17 and 34 times the human daily dose. There are no studies in pregnant women. Baclofen should be used in pregnancy only if the benefit clearly justifies the potential risk to the fetus.

FIRST®- Baclofen 5 Compounding Kit components have a two - year expiration.** Prior to compounding, store FIRST®- Baclofen 5 Compounding Kit at room temperature 15º – 30ºC (59º – 86ºF). Based on real time temperature and humidity testing, *compounded* FIRST®- Baclofen 5 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 a) for 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, c) for the absence of the specified microorganisms *Esherichia 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®- Baclofen 1 Compounding Kit is available as follows:
4 FL OZ (120 mL) as dispensed (NDC 65628-100-04)

FIRST®- Baclofen 5 Compounding Kits are available as follows:
2 FL OZ (60 mL) as dispensed (NDC 65628-101-02)
4 FL OZ (120 mL) as dispensed (NDC 65628-101-04)

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

℞ ONLY

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Manufactured for:

CUTISPHARMA®
Transforming Compounding through Innovation™

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Grape Flavor

ORAL SUSPENSION ®

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