

# FIRST®-Baclofen **R**

## Baclofen 1 mg/mL or 5 mg/mL in FIRST® -Grape II Suspension Compounding Kit

### FOR PRESCRIPTION COMPOUNDING ONLY

#### DESCRIPTION

Each FIRST® - Baclofen Compounding Kit is comprised of baclofen, USP powder and 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 either 1 mg/mL or 5 mg/mL FIRST® Baclofen Oral Suspension.\*\*

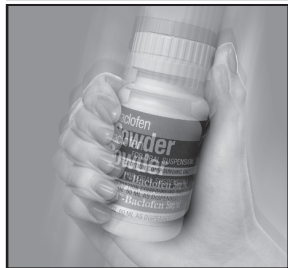
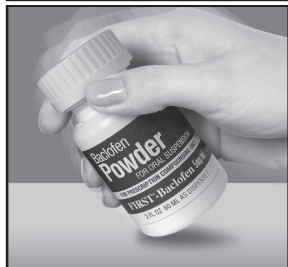
#### How Supplied and Compounding Directions

Concentration (Size as dispensed)	1 mg/mL (120 mL)	5 mg/mL (60 mL)	5 mg/mL (120 mL)
NDC#	65628-100-04	65628-101-02	65628-101-04
Baclofen, USP Powder	0.12 g	0.3 g	0.6 g
Diluent (FIRST® - Grape II Suspension)	120 mL	60 mL	120 mL

#### TO THE PHARMACIST

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

Please note that these photos may not be representative of the product supplied. Please refer to the actual bottle labels for contents and reconstituted concentration.



1. FIRST®- Baclofen Compounding Kit contains pre-measured baclofen, USP powder and Diluent.
2. **Important** - Hold the neck of the bottle containing baclofen, USP 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, USP powder bottle**. Replace the cap and shake the baclofen, USP powder bottle well for approximately 60 seconds.
4. Empty the remaining Diluent **into the baclofen, USP powder bottle and allow the Diluent to drain for 10 seconds**. Replace the cap and shake the baclofen, USP powder bottle well for approximately 60 seconds.
5. Dispense the Baclofen oral suspension in the barcoded powder bottle to the patient.
6. **Instruct patient to shake the bottle well 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 increased 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.

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

Prior to compounding, store FIRST®- Baclofen 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 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®- Baclofen Compounding Kits are available as follows:  
1 mg/mL 120 mL as dispensed (NDC 65628-100-04)  
5 mg/mL 60 mL as dispensed (NDC 65628-101-02)  
5 mg/mL 120 mL as dispensed (NDC 65628-101-04)

\* Certificate of analysis on file

\*\* Equivalent to USP Baclofen Compounded Oral Suspension

\*\*\* Data and documentation on file

#### **R** ONLY

Revised: March 2020

Manufactured for:

 **azurity**<sup>™</sup>  
pharmaceuticals  
Wilmington, MA 01887 USA  
www.azurity.com

