



To Whom it May Concern:

This medication has been custom compounded and is not commercially available. As such, this medication is not assigned a National Drug Code (NDC) number.

No NDC number exists for this medication, nor is a NDC number required by the FDA or any other regulatory agency. *“A compounded drug, i.e., a drug compounded by a pharmacist on order of a licensed practitioner, is not subject to these regulations and does not receive an NDC number. Such compounding is considered the practice of pharmacy/medicine.”* Source: FDA, 1995, letter to Senator Cochran.

- This medication was made and dispensed in compliance with all state and federal regulations and the U.S. Pharmacopeia.
- By law, compounded medications or their ingredients do NOT require FDA-approval. There is NO FDA approval process for compounded prescriptions or the ingredients they contain.
- This medication is dispensed on the written order of a licensed prescriber and is only available by prescription.
- A compounded medication is NOT a generic drug, a brand name drug or an investigational drug.
- There is no average wholesale price or other published price for a compounded medication.
- O'Brien Pharmacy is accredited by the Pharmacy Compounding Accreditation Board. PCAB accreditation is recommended by the American Medical Association and all major pharmacy organizations including the United States Pharmacopeia and National Association of Boards of Pharmacy.
- *In accordance with the policy benefits manual, all supporting documentation has been supplied and all requirements have been met.*

O'Brien Pharmacy

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