



*Acellular Product Derived from Wharton's Jelly Mesenchymal  
Stem Cells*

## **Product Information and Preparation Instructions**

### **CONTENTS / HOW SUPPLIED**

This package contains exosome rich conditioned media harvested from Mesenchymal Stem Cells (MSCs) derived from Wharton's Jelly. Wharton's Jelly MSCs were cultured in aseptic conditions after being collected from eligible donors.

The donor tissue has been determined eligible for use by a licensed Medical Director according to the criteria listed in the Donor Eligibility section below.

### **PRODUCT DESCRIPTION**

BelloXO™ is an acellular product derived from Wharton's Jelly MSCs. It is received in a serum vial. If the serum vial is open, do not use. BelloXO™ is intended for a single patient, one time use only.

**Once opened, ReBellaXO™ must be used immediately or discarded.**

### **DONOR ELIGIBILITY**

The donor of the tissue used to produce this product is eligible to donate tissue for use based on meeting the following criteria:

1. Donors are pre-screened through medical record review and evaluation of pre-natal tests.
2. Eligibility contingent on confirmation of
  - Behavioral risk assessment
  - Physical assessment
  - Donor medical history
  - Blood test results
  - Communicable disease testing

Discussions with physicians and/or the donor mother are conducted to identify circumstances that may lead to the exclusion of the donor or donated tissue. The blood sample test results, donor medical history, behavior risk assessment, physical assessment, and information from other sources or records, which may pertain to donor suitability, have been evaluated by a Medical Director. The results are used to determine that the donor suitability criteria at the time of tissue recovery have been met, and that the tissue is acceptable for use.

### **RECOVERY**

Tissue processing and MSC recovery is performed by General Therapeutics LLC, Cleveland Heights, OH, USA using aseptic techniques. At the time of recovery, medical records are collected and reviewed as part of the donor eligibility. Technical quality assurance standards are rigorously maintained.

### **PRODUCT MANUFACTURING AND DISTRIBUTION**

BelloXO™ is manufactured by General Therapeutics LLC, (Cleveland Heights OH, USA) and is distributed by Regen Suppliers LLC (Canyon Lake, CA). All inquiries should be directed to +1 (888) 568-6909 or support@regensuppliers.com