

PRODUCT STORAGE

It is the responsibility of the end user to document and maintain BelloXO™ in its original packaging. BelloXO™ should be at 4-20° C prior to use. BelloXO™ should not be stored at 4-20°C for an excess of 14 days.

INDICATIONS

BelloXO™ is intended for topical use only as determined by a physician.

CONTRAINDICATIONS

In order to reduce the risk of complications, BelloXO™ should not be administered in the presence of active infections. BelloXO™ should not be administered to pregnant women, women planning to be pregnant within four months, or women currently breast feeding. As general practice, it is best to have IM Benadryl and Epinephrine available in the event of an anaphylactic event.

ADVERSE REACTIONS

Although donor cells are evaluated and processed, the donor screening methods are limited and may not detect all diseases. Therefore, complications of allograft may include, but are not limited to:

- Transmission of diseases of unknown etiology
- Transmission of unknown infectious agents such as viruses, bacteria and fungi

Adverse reactions or outcomes that potentially involve the use of BelloXO™ should be reported immediately to Regen Suppliers.





RECOMMENDED INSTRUCTIONS FOR USE OF BelloXO™

These recommendations are designed only to serve as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

PREPARATION INSTRUCTIONS

1. Maintain BelloXO™ at -20°C or colder for long term storage and transfer to 4°C prior to use.
2. Remove the vial from the packaging.
3. Allow contents to thaw at room temperature until flowable.
4. BelloXO™ is ready for use.

Warnings

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|  | Do not use if the vial integrity has been violated , is opened or damaged, or if mishandling has caused possible damage or contamination. BelloXO™ should not be administered in the presence of active infections. BelloXO™ should not be administered to pregnant women, women planning to become pregnant within four months, or women currently breast feeding . |
|  | Store at a temperature of -20°C or colder for long term storage. Store at temperature of 4°C for short term storage. |
|  | Once the expiration date on the label has been reached, the allograft must be discarded. |
|  | BelloXO™ is intended for a single patient, one time use only |

POST UTILIZATION, HANDLE AND DISPOSE OF ALL UNUSED PRODUCT AND PACKAGING IN ACCORDANCE WITH ACCEPTED MEDICAL PRACTICES & PROCEDURES. IN ADDITION TO APPLICABLE LOCAL, STATE, AND FEDERAL LAWS AND REGULATIONS.