BioXsomes™

Cryopreserved Acellular Exosome Product

Derived from Wharton's Jelly and Amniotic Fluid

Read this entire package insert carefully prior to use.

Product Use

BioXsomes™ is an advanced Exosome Technology product that is derived from human placental Amniotic Fluid & Wharton's Jelly. **BioXsomes™** is considered an injectable therapeutic that can be used for wound care, orthopedics, and pain management.

The licensed, healthcare professional receiving this product shall have sole discretion and responsibility to determine in accordance with applicable laws and professional standards the suitability of the product for any and all uses to which the licensed professional intends. The healthcare professional assumes all responsibility and liability with respect to the product.

For licensed professionals, sale and use only. Single patient use only, on a single visit.

For use under Florida Law Only. This product is manufactured, distributed, and used by licensed healthcare professionals in the State of Florida.

Storage and Expiration

BioXsomes™ is stored cryopreserved and shipped frozen (dry ice / equivalence to temperatures of -65 to -80°C) the product should remain frozen and may be stored at this temperature until product best-by date.

BioXsomes™ may be stored up to the best-by date as long as the product vial and seal has not been breached, and temperature maintained. If you find packaging has been breached in any way or that temperature has not been maintained, then DO NOT USE and dispose of appropriately.

The best-by date is found on the Certificate of Analysis in MM/YYYY format, where the date is two (2) years from the date of manufacture and is extended through the last day of the month.

General Instructions

Prior to the provider performing stem cell therapy, treatment, providers are required to obtain a consent form signed by the patient. The consent form must include:

1. The nature and character of the proposed treatment, including the treatment's United States Food and Drug Administration approval status.
2. The anticipated results of the proposed treatment.
3. The recognized possible alternative forms of treatment.
4. The recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including nontreatment.

A health care provider who conducts stem cell therapy pursuant to this section shall provide a patient who is being treated with stem cell therapy with the following written notice before performing the therapy: "THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW. This health care practitioner performs one or more stem cell therapies that have not yet been approved by the United States Food and Drug Administration.

Product Instructions:

1. For patient consent and treatment go to: clinicalstudyresearch.com/admin-login
2. Login with your user credentials.
3. Open product package and remove product vial from packaging.
4. Allow product to thaw at room temperature or hold in hand until ice has completely melted (approx. 5 minutes).
5. After contents are thawed, place vial in upright position and gently tap it on hard surface to transfer all vial contents to the bottom.
6. Best practice to extract fluid from vial is with an 18-25G needle. Remove cap, secure a needle to syringe of choice, aspirate fluid into syringe.
7. Product must be used upon thawing.
8. This product must not be used under any of the following circumstances:
   - If the vial container seal is damaged or not intact or has any physical damage;
   - If the container label or packaging is severely damaged, not legible or is missing; or
   - If the best-by date shown on the labeling has passed.

Product Testing

BioXsomes™ is processed from human amniotic fluid and umbilical cord that were donated from consented living donors with normal, healthy full-term pregnancies. Each donor is carefully screened and tested. Comprehensive medical and social histories of the donors are obtained and tested to minimize potential risks of disease transmission to recipients. Infectious disease testing is performed at a certified laboratory in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 CFR Part 493, and FDA requirements. Each donor is tested for a serology panel at, or near the time of donation. All results must be reported negative / non-reactive. In addition to the required donor testing, donor screening for exposure to other communicable diseases may have been completed. Risk factors are screened and are evaluated on a case-by-case basis by the Medical Director.

Each product lot is tested post-processing to demonstrate the absence of bacterial and fungal pathogens and is non-pyrogenic.

Required donor testing:	**Donor Screening:**
1. Human Immunodeficiency Virus Type 1 Nucleic Acid Test, Hepatitis B Virus Nucleic Acid Test, Hepatitis C Virus Nucleic Acid Test (HIV/HBV/HCV-NAT) 2. HIV-I/II Antibodies + group O 3. Hepatitis C Virus (HCV) Antibodies 4. Hepatitis B Surface Antigen (HBsAg) 5. Hepatitis B Core Antibodies (HBcAb) 6. Treponema pallidum (Syphilis) 7. WNV-NAT 8. Human T-Cell lymphotropic Virus I/II Antibodies* 9. CMV Total Antibodies*	The donor screening, in addition to donor testing, may be completed via social and medical questions. The physician utilized available relevant medical records which may have included but was not limited to: Donor risk assessment interview, medical/hospital records, donor physical assessment, cultures and prenatal serologies, radiology/pathology, and other records if available and pertinent.
	Product testing:
	Sterility <USP 71> = No growth
	Endotoxin <USP 85> = NMT 0.5 EU/mL
	Ingredient cultures positive for clostridium, fungi (yeasts, molds,) or streptococcus pyogenes (Group. A strep) will be discarded.

*If IgG positive and IgM negative, then testing indicates a past infection and result is acceptable.

BioXsomes™ are prepared from donors who have been determined eligible based on screening and testing results. The determination of donor eligibility is the responsibility of BioXtek's Medical Director.

Processing

Human placental tissue is recovered using aseptic technique and sterile instruments to minimize any bioburden contamination. The placental tissue is donated and acquired via a network of qualified and trained recovery partners, using the most stringent screening and recovery protocols in a controlled environment, minimizing and limiting the risks of disease transmission at every step of the process. The tissue is ethically sourced and are not derived from aborted fetuses or embryos post-abortion.

This product was manufactured in a classified, certified cleanrooms that utilize high-efficiency air filtration system to reduce the risk of contamination. **BioXsomes™** is processed from a single donor., vialed, and sealed using aseptic technique, all in accordance with our proprietary BioPür™ process. **BioXsomes™** is sterile by aseptic processing and filtered through a 0.2µm filtration step.

Packaging and Labeling

BioXsomes™ is packaged in 2mL glass serum vials, rubber stoppered, and crimp sealed and capped for sterility assurance. The vial is labeled with the volume (mL) and lot number for product identification and traceability. The vial is placed into a peel pouch and sealed for protection. The final packaging is affixed with a front & back label. The serial number is unique to each individual product and is in the format “lot number-unit number”.

Regulatory Status

BioXsomes™ is approved for use in Florida only under the House Bill 1617 and the Senate Bill 1768. authorizes certain licensed physicians in Florida (Specifically Chapters 458 and 459, therefore this includes Ch.458- MD's, PA's and Ch. 459, DO's) to perform stem cell therapies that have not been approved by the United States Food and Drug Administration (FDA), but only under limited and defined circumstances. These therapies may only be administered when they fall within the provider’s scope of practice and are specifically related to orthopedics, wound care, or pain management

Customer Returns and Concerns

Direct all customer complaints to BioXtek using the contact information below. Provide information such as lot number / serial number, description of event, and provide photos or documentation. If product is not used, do not use. Product shall be returned to BioXtek for further investigation.

Reporting Adverse Events

If an adverse reaction is encountered, stop using product immediately and report to BioXtek using the contact information indicated below. Be specific about the nature of the adverse event, including when it occurred, the symptoms experienced, and any other relevant details.

Precautions

Proper storage is the responsibility of the end user. Do not re-sterilize. Do not use if vial seal is broken.

This product is for a single patient; one time use only. Once thawed and opened, the product must be used within 30 minutes or disposed of appropriately.

Same and similar potential medical conditions, surgical conditions, or complications that apply to any surgical procedure may occur during or following implantation or application of this allograft. The health professional or surgeon is responsible for informing patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any human tissue allograft, the potential for transmission of infectious agents may exist.

Contraindications

BioXsomes™ has not been tested on pregnant woman. BioXsomes™ is not recommended for use in immune compromised patients or used on or around areas of infection.

Warranty

BioXsomes™ provided to the licensed professional, is provided "as is" without any warranties, either express or implied, including but not limited to the implied warranties of merchantability, fitness for a particular purpose, or non-infringement of third-party proprietary rights, unless such disclaimers are prohibited by law.

BioXtek is not liable for the intended use of any of its products. BioXtek does not define, suggest, alter, or approve any "practice of medicine" performed by the administering professional(s).

This product is intended for topical use only and is unique in nature. It is not covered under liability laws applicable to standard products. No implied warranties of merchantability or fitness for a particular purpose apply to this product. Additionally, there are no implied warranties regarding defects in the product that cannot be identified, corrected, or prevented through reasonable use of available scientific methods or techniques. All warranties, whether express or implied by law or otherwise, including implied warranties of merchantability or fitness for a particular purpose, are hereby disclaimed.

Contact

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