EUROPAXEL®

MERMISI

High-Precision Nanotechnology for Superior Oncology Outcomes

Europaxel is a solvent-free, albumin-bound nanoparticle formulation of paclitaxel (130 nm) designed to enhance drug delivery directly to tumor sites while significantly improving the safety profile compared to solvent-based paclitaxel.

PRODUCT COMPOSITION

- **ACTIVE INGREDIENT:**
  100 mg Paclitaxel formulated as albumin-bound nanoparticles.
- **CONCENTRATION:**
  After reconstitution, each mL contains 5 mg paclitaxel.
- **FORMULATION:**
  Lyophilized powder for dispersion for infusion (Intravenous Use).
- **EXCIPIENTS:**
  Human serum albumin (contains sodium caprylate and N-acetyl-L-tryptophan).

WORLD-CLASS MANUFACTURING & CERTIFICATION

- **MANUFACTURER:**
  Produced by Kexing Biopharm Co., Ltd. (China).
- **EU GMP CERTIFIED:**
  The manufacturing facility is fully compliant with European Union Good Manufacturing Practice (EU GMP) standards, as certified by the Norwegian Medical Products Agency (Certificate No: 23/28995-19).
- **HIGH-QUALITY API:**
  The Paclitaxel API is manufactured by Fujian South Pharmaceutical Co. Ltd., which holds the following international certifications:
- **US FDA REGISTERED:**
  Establishment Identifier 3008467694.
- **GLOBAL COMPLIANCE:**
  Also certified by COFEPRIS (Mexico) and EDQM (Europe).

EUROPEAN UNION GMP | FDA U.S. FOOD & DRUG ADMINISTRATION | COFEPRIS | edqm

EUROPAXEL®

MERMISI

Clinical Advantages & Regulatory Equivalence

The nab™ Technology Advantage

TARGETED DELIVERY:
Utilizes the gp60 receptor-mediated transcytosis and the SPARC pathway (Secreted Protein, Acidic and Rich in Cysteine) to concentrate paclitaxel within the tumor microenvironment.

SOLVENT-FREE SAFETY:
By eliminating Cremophor EL, Europaxel removes the primary cause of severe hypersensitivity reactions.

NO PREMEDICATION:
Routine premedication with steroids or antihistamines is not required.

RAPID INFUSION:
Administered over just 30 minutes, increasing clinic efficiency and patient comfort.

EU REGULATORY EQUIVALENCE

Europaxel is the same product registered in the European Union under the brand name Apexelsin.

EMA AUTHORIZATION: Authorized by the European Medicines Agency (EMA) under product number EMEA/H/C/005997.

GENERIC REFERENCE: Registered as a generic of the reference medicine Abraxane, ensuring identical efficacy and safety profiles.

METASTATIC BREAST CANCER:
Monotherapy for patients who have failed first-line treatment.

NON-SMALL CELL LUNG CANCER (NSCLC):
First-line treatment in combination with carboplatin.

METASTATIC PANCREATIC ADENOCARCINOMA:
First-line treatment in combination with gemcitabine.

MERMISI
TBILISI GEORGIA

MARKET AUTHORIZATION HOLDER: MERMISI LLC, TBILISI, GEORGIA.