- Unexplained infertility
- Sperm motility
- Comfortable environment in vagina (sperm survival)

Medical Device

Quality Assurance ISO 9001 - ISO 13485

MADE IN ITALY

INFERTILITY

DESCRIPTION

FEMAFERTI GEL formulation, based on sugars, mineral salts, creatine, carnitine, hyaluronic acid and lactic acid:
- Creates an optimal environment for spermatozoa
- Helps in maintain a suitable pH for natural conception
- Is characterized by seminal fluid-compatible osmolality.

FEMAFERTI GEL should be used during the ovulation phase 5 minutes before sexual intercourse.

THERAPEUTIC INDICATIONS

- **Unexplained infertility**
- **Reduced cervical mucus receptivity**
  - **Low production**
  - **Abnormal pH**
- **Low sperm survival**

PRESENTATION

Each box of **FEMAFERTI GEL** contains 6 single dose applicators of 5 mL each one.

INGREDIENTS

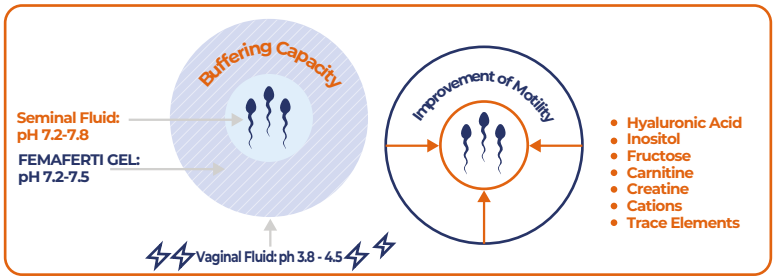
Aqua, Glucose, Fructose, Sodium Hyaluronate, Magnesium Citrate, Calcium Piruvate, Sorbitol, Lactic Acid, Citric Acid, Inositol, Potassium Citrate, Sodium Bicarbonate, Zinc Gluconate, Carnitine, Creatine, Sodium Chloride, DMDM Idantoin, Sodium hydroxide, Phenoxyethanol, Ethilexylglycerin, Hydroxyethylcellulose

REGULATORY STATUS

- Class I
- Free sale certificate
- Certificate of origin (at the time of invoicing)
- ISO 13485 certificate
- US FDA registration

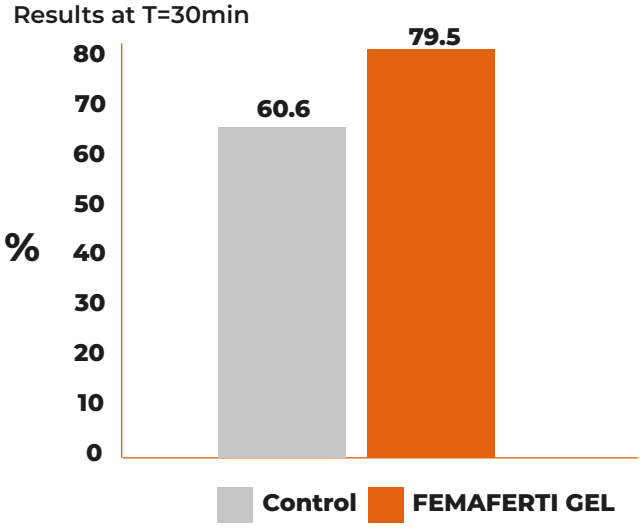
PLUS

FEMAFERTI GEL mimics seminal fluid composition generating a comfortable environment for spermatozoa and giving adequate energy for sperm motility



CLINICAL TEST FOR SPERM MOTILITY IMPACT OF FEMAFERTI GEL

Motility PR *(sperm that are swimming in a mostly straight line or large circle)*:
% of spermatozoa
Results at T=30min



Control → without gel
FEMAFERTI GEL → FEMAFERTI GEL : Semen=1:1

CLINICAL TEST

RISK ANALYSIS - according to UNI CEI EN ISO 14971
BIOCOMPATIBILITY – according to UNI EN ISO 10993:
- CYTOTOXICITY for DIRECT CONTACT - according to ISO 10993-5:2009
- DELAYED HYPERENSIVITY TEST (GPMT) - according to ISO 10993-10:2010
- VAGINAL IRRITATION TEST - according to ISO 10993-10:2010

CLINICAL EVALUATION – according to MEDDEV 2.7-1
STABILITY - according to ICH Guidelines
- ACCELERATED STABILITY STUDY

Capricorn life sciences