

UTREVA

(PROGESTERONE VAGINAL GEL 8% w/w) **Composition:** Each g of vaginal gel contains: Progesterone IP 80 mg Gel Base Q.S. **Indications** UTREVA is indicated for progesterone supplementation or replacement as part of an Assisted Reproductive Technology ("ART") treatment for infertile women with progesterone deficiency. **Dosage and administration:** Assisted Reproductive Technology UTREVA is administered vaginally at a dose of 90 mg once daily in women who require progesterone supplementation. UTREVA is administered vaginally at a dose of 90 mg twice daily in women with partial or complete ovarian failure who require progesterone replacement. If pregnancy occurs, treatment may be continued until placental autonomy is achieved, up to 10 to 12 weeks. **Method of administration:** UTREVA is administered vaginally. **Contraindication:** UTREVA should not be used in individuals with any of the following conditions: Undiagnosed vaginal bleeding, Known sensitivity to UTREVA (progesterone or any of the other ingredients), Liver dysfunction or disease, Known or suspected malignancy of the breast or genital organs, Missed abortion, Active thrombophlebitis or thromboembolic disorders, or a history of hormone-associated thrombophlebitis or thromboembolic disorders **Warnings and precautions:** **Pregnancy and lactation:** UTREVA has been used to support embryo implantation and maintain pregnancies through its use as part of ART treatment regimens. Nursing mothers: Detectable amounts of progestins have been identified in the milk of mothers receiving them. The effect of this on the nursing infant has not been determined. **Adverse drug reactions:** UTREVA is generally well-tolerated. Following adverse events have been reported during progesterone vaginal gel 8% therapy: Body as a Whole: Abdominal Pain., Central and Peripheral Nervous: Dizziness, Headache, Gastro-Intestinal System: Constipation, abdominal pain, Diarrhea, Nausea, Vomiting, Musculo-Skeletal System: Arthralgia, Psychiatric: Depression, Libido Decreased, Nervousness, Somnolence, Reproductive, Female: Breast Enlargement, Dyspareunia, Moniliasis Genital, Perineal Pain, Vaginal Discharge, Skin and Appendages: Pruritus Genital, Urinary System: Nocturia. Last updated on 3/8/2020. For further information, please refer full prescribing information.

(For the use of a registered medical practitioner or hospital or laboratory only)