UTAVET UTERINE PESSARIES

(Sulphathiazole, Penicillin G, Streptomycin, Ethinyloestradiol)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Utavet Uterine Pessaries

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sulphathiazole ……..…….. 1750mg
Penicillin G ……..…….... 100000 IU
Streptomycin (as Sulphate)…….…….……. 50mg
Ethinyloestradiol ……..…….. 0.5mg

3. PHARMACEUTICAL FORM

Intra-uterine Pessaries

4. CLINICAL INFORMATION

4.1. Target species

Cattle and Buffaloes
Goat and Ewes
Mares

4.2. Indications for use specifying the target species

An infectious disorder resulting from abortion, premature or difficult labor, cesarean section, uterine prolapse, retained placenta, or bacterial infections of the genital tract.

4.3. Contraindications

- Contraindicated in pregnant animals due to Ethinyloestradiol, which may cause hormonal imbalances and fetal abnormalities.
- Should not be administered to animals with known hypersensitivity to Sulphathiazole, Penicillin G, or Streptomycin, as severe allergic reactions, including anaphylaxis, may occur.
- Caution is advised in animals with renal impairment, as Streptomycin can be nephrotoxic and may worsen kidney function.
- Not recommended in cases of severe systemic infections; systemic antibiotic therapy should be preferred over local application.
- Should not be used when bacterial resistance to Penicillin or Streptomycin has been documented, as ineffective treatment may lead to complications.
- Avoid use in animals with severe uterine wall damage, as it may worsen inflammation or delay healing.
- Ethinyloestradiol necessitates caution in hormone-sensitive conditions, such as cystic ovarian disease, as it may exacerbate hormonal imbalances.
- In lactating animals, use should be carefully considered, as antibiotic residues may be excreted in milk, posing risks to suckling offspring.

4.6. Adverse reactions (frequency and seriousness)

- **Allergic Reactions** – Hypersensitivity to Sulphathiazole, Penicillin G, or Streptomycin may cause skin rashes, swelling, difficulty breathing, or anaphylaxis in severe cases.
- **Local Irritation** – Application may lead to irritation, redness, swelling, or discomfort in the uterine lining, especially in animals with pre-existing inflammation.
- **Gastrointestinal Disturbances** – Possible side effects include diarrhea, nausea, or loss of appetite due to systemic absorption of antibiotics.
- **Nephrotoxicity** – Streptomycin can have toxic effects on the kidneys, leading to impaired renal function in sensitive animals.
- **Hormonal Imbalance** – Ethinyloestradiol may cause irregular estrous cycles, temporary infertility, or hormonal disturbances in treated animals.
- **Secondary Infections** – Prolonged use may disrupt the natural uterine flora, increasing the risk of opportunistic infections.
- **Milk Contamination** – Antibiotic residues may be excreted in milk, potentially affecting suckling offspring and leading to antibiotic resistance concerns.
- **Ototoxicity** – Streptomycin may contribute to hearing impairment or balance issues in some cases due to its ototoxic properties.

4.7. Dosage and administration route

Animal	Prophylaxis	Treatment
Cattle , Buffaloes and Mare	2-4 Utavet Pessaries	4-8 Utavet Pessaries
Goat and Ewes	1-2 Utavet Pessaries	2-4 Utavet Pessaries

- **Sanitization:** Clean the perineal area and vulva with an antiseptic solution to reduce the risk of infection.
- **Glove Use:** Wear sterile gloves to maintain hygiene and prevent contamination.
- **Insertion:** Gently insert the pessary into the uterus using a clean, lubricated hand or a specialized uterine applicator. For larger animals like cattle, the pessary may need to be guided manually into the uterus.
- **Post-Administration Care:** Allow the animal to rest, and monitor for any signs of discomfort, irritation, or abnormal discharge. Ensure the environment remains hygienic to prevent secondary infections.
- **Precautionary Measures:** Avoid applying excessive force during insertion to prevent injury to the uterus. In difficult cases, it is advisable to consult a veterinarian for assistance.

4.8. Overdose (symptoms, emergency procedures, antidotes), if necessary

Data not available. Do not exceed recommended doses

4.9. Withdrawal period:

Meat and offals: 7 days

5. PHARMACOLOGICAL PROPERTIES

5.1. Sulphathiazole

- **Pharmacodynamics:**
  Sulphathiazole is a bacteriostatic antibiotic that inhibits bacterial folic acid synthesis by blocking the enzyme dihydropteroate synthase. This action prevents bacterial growth and reproduction. It is effective against a broad range of Gram-positive and Gram-negative bacteria and is used in treating uterine infections in animals.

- **Pharmacokinetics:**
  After intrauterine administration, Sulphathiazole is absorbed into the uterine tissues and fluids. Its distribution primarily occurs within the local uterine environment, with minimal systemic absorption. The drug is metabolized in the liver, and its metabolites are excreted in the urine. Its half-life in the body may vary based on kidney function and the animal's health status.

5.2. Penicillin G

- **Pharmacodynamics:**
  Penicillin G works by inhibiting bacterial cell wall synthesis. It binds to penicillin-binding proteins (PBPs) in bacterial cells, interfering with their ability to cross-link peptidoglycan layers in the cell wall. This leads to cell lysis and death. Penicillin G is effective against Gram-positive bacteria and some Gram-negative bacteria, particularly those causing uterine infections.
- **Pharmacokinetics:**
  When administered intrauterine, Penicillin G acts locally within the uterus to target infections. It is absorbed into the uterine tissues, and while it has limited systemic absorption, the drug can be detected in the bloodstream in trace amounts. Penicillin G is primarily excreted unchanged in the urine, and its half-life is relatively short, about 30 minutes to 1 hour.

5.3. Streptomycin (as Sulphate)

- **Pharmacodynamics:**
  Streptomycin inhibits bacterial protein synthesis by binding to the 30S ribosomal subunit, causing misreading of mRNA and defective protein production, ultimately leading to bacterial cell death. It is effective against various Gram-negative and some Gram-positive bacteria, often used in treating infections in the uterus.
- **Pharmacokinetics:**
  Following intrauterine administration, Streptomycin remains localized in the uterine tissues. The absorption into the bloodstream is minimal, and it mainly acts within the infected area. It is eliminated via the kidneys in unchanged form. The half-life is approximately 2 to 3 hours, but careful monitoring is needed in cases of renal insufficiency.

5.4. Ethinyloestradiol

- **Pharmacodynamics:**
  Ethinyloestradiol is a synthetic estrogen that binds to estrogen receptors in the uterus, regulating reproductive processes. It helps to manage hormonal imbalances that may contribute to uterine disorders in animals, ensuring optimal uterine health and functionality.
- **Pharmacokinetics:**
  After intrauterine administration, Ethinyloestradiol acts locally on the reproductive tissues. It is absorbed through the uterine lining and exerts its effects without significant systemic distribution. It undergoes hepatic metabolism and is excreted primarily in urine as metabolites. The half-life of Ethinyloestradiol is about 10 to 20 hours.

6. PHARMACEUTICAL INFORMATION

6.1. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the container: use immediately, do not store.

6.2. Special precautions for storage

Store below 25°C
Protect from light and moisture.
Keep out of reach of children.
Care should be taken to ensure proper storage and handling to maintain the integrity of the product.

6.3. Nature and composition of primary conditioning

Alu/PVC blister of 20's.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS
UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Any unused veterinary medicinal products or waste materials derived from such medicinal products should be disposed of in accordance with local requirements and placed in appropriate collection and disposal systems for unused or expired medicinal products.

7. MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 014103

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 01-08-1993

10. DATE OF REVISION OF THE TEXT

28-01-2025

MANUFACTURED BY:

NAWAN LABORATORIES (PVT) LTD. | 136, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan.