1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metricure 500 mg Intrauterine Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 19 g polyethylene syringe contains:

Active substance:
Cephapirin (as cephapirin benzathine) 500 mg

Excipients:

Qualitative composition of excipients and other constituents
Macrogol cetostearyl ether-20
Macrogol cetostearyl ether-12
Hydrogenated castor oil
Triglycerides, medium chain

A creamy, oily and sterile suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (Cows).

3.2 Indications for use for each target species

For the treatment of subacute and chronic endometritis in cows (at least 14 days after parturition) caused by bacteria sensitive to cephapirin. It can also be used to treat repeat breeder cases (more than three unsuccessful inseminations) if bacterial infections are suspected to be the cause of the fertility problem.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Sensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances are occasionally serious.

People with known hypersensitivity to cephalosporins should avoid contact with the veterinary medicinal product.

Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions.

If you develop symptoms following exposure, such as a skin rash, you should seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention. Accidental spillage on the skin should be washed off immediately with soap and water.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (Cows):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Allergic reaction

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not use during pregnancy.
Can be used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Not to be administered concurrently with other intrauterine antibiotic preparations.

3.9 Administration routes and dosage

Intrauterine use.
The contents of one the veterinary medicinal product syringe should be introduced into the lumen of the uterus using the disposable catheter provided as follows:
1. The veterinary medicinal product may settle but can be re-suspended by gentle shaking into a homogeneous suspension.
2. Fix the syringe to the catheter.
3. Take the cervix of the uterus into one gloved hand introduced into the rectum.
4. Introduce the catheter through the cervix into the lumen of the uterus, by gentle oscillating movements of the cervix.
5. Inject the veterinary medicinal product.

The veterinary medicinal product is a single use syringe.

One treatment with the veterinary medicinal product is usually sufficient for a complete cure.
In animals that have been inseminated, the veterinary medicinal product may be used at one day after insemination. In cases of pyometra, pre-treatment with prostaglandins is recommended in order to induce luteolysis and remove debris from the uterine cavity.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Product supplied in a single dose syringe therefore overdose is unlikely to occur.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal: 24 hours

Milk: Zero days.
Milk for human consumption may be taken from animals during treatment.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG51AA05

4.2 Pharmacodynamics

Cephapirin, a first-generation cephalosporin, is a broad spectrum antibiotic with bactericidal action against gram-positive and gram-negative bacteria. Cephapirin is resistant to the action of penicillinase and is active in an anaerobic environment such as is encountered in an infected uterus. After a single treatment with the veterinary medicinal product, concentrations of cephapirin in endometrial tissue above the MIC of sensitive bacteria are maintained for at least 24 hours.

4.3 Pharmacokinetics

After intrauterine treatment, absorption is low, which is reflected by the low plasma levels of cephapirin observed shortly after treatment. Twelve hours after treatment, cephapirin levels in plasma are below detectable levels.

After intrauterine administration of the veterinary medicinal product, high cephapirin concentrations are observed in the endometrium (10.4µg/g at 8 hours after treatment).

Endometrium concentrations can be observed up to 24 hours (0.81µg/g).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

5.3 Special precautions for storage

Do not store above 25^{o}C.

5.4 Nature and composition of immediate packaging

Polyethylene syringe barrel with plunger and cap containing 19 g of suspension.
Each pack contains: 10 syringes, 10 intrauterine catheters and 10 disposable gloves.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/053/001

8. DATE OF FIRST AUTHORISATION

02/11/2001

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

15/07/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).