SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metricure 500 mg Intrauterine Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 19 g syringe contains:

Active substance:

Cefapirin 500 mg (as cefapirin benzathine)

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

The veterinary medicinal product is indicated for the treatment of subacute and chronic endometritis in cows (at least 14 days after parturition) caused by bacteria sensitive to cefapirin.

3.3 Contraindications

Do not use in cases of hypersensitivity to cephalosporins or other beta-lactam antibiotics.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

<u>Special precautions to be taken by the person administering the veterinary medicinal product to animals:</u>

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

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

Do not handle this veterinary medicinal product if you know you are sensitised or if you have been advised not to work with such preparations.

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, 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. Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (cows):

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

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 its local representative 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:

The veterinary medicinal product is not indicated for use during pregnancy but 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 syringe should be introduced into the lumen of the uterus using the disposable catheter provided as follows:

- 1. Shake the syringe before use.
- 2. Fix the syringe to the catheter.
- 3. Hold the cervix of the uterus with 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 contents of the syringe.

Depending on the response, a second treatment 7-14 days later may be required in some cases if clinical signs persist.

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 prostaglandin 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)

The veterinary medicinal product is supplied as 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: 1 day.

Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG51AA05.

4.2 Pharmacodynamics

Cefapirin, a first generation cephalosporin, is a broad spectrum antibiotic with bactericidal action against gram-positive and gram-negative bacteria. Cefapirin is resistant to the action of penicillinase.

4.3 Pharmacokinetics

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

After intrauterine administration of the veterinary medicinal product, high cefapirin concentrations are observed in the endometrium.

Cefapirin concentrations in the endometrium can be observed for up to 24 hours.

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 °C.

Syringes are for single use only. Keep the syringe in the outer carton.

5.4 Nature and composition of immediate packaging

High density polyethylene syringe barrel with low density polyethylene plunger and cap containing 19 g of suspension, packed in boxes of 12 syringes. Intrauterine catheters are provided for administration.

Pack size:

Cardboard box of 12 syringes.

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

Medicines should not be disposed of via wastewater.

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 International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4099

8. DATE OF FIRST AUTHORISATION

14 October 2003

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

June 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 29 September 2025