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
Oily base to	19 g	

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Intra-uterine suspension.
A creamy, oily and sterile suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (Cows).

4.2 Indications for use, specifying the 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.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals
Use of the 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 sensitisation (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.

1. Do not handle this product if you are sensitised or if you have been advised not to work with such compounds.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Allergic reactions have been observed in very rare cases.
The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment).
- common (more than 1 but less than 10 animals in 100 animals).
- uncommon (more than 1 but less than 10 animals in 1,000 animals).
- rare (more than 1 but less than 10 animals in 10,000 animals).
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The product is not to be used during pregnancy but can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Not to be administered intra-uterinely concurrently with other antibiotic preparations.

4.9 Amounts to be administered and administration route

The contents of one Metricure syringe should be introduced into the lumen of the uterus using the disposable catheter provided as follows:

1. The 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 Metricure.

One treatment with Metricure is usually sufficient for a complete cure.
In animals that have been inseminated, Metricure 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Milk: zero hours.
Milk for human consumption may be taken from animals during treatment.

Meat: 24 hours
Animals intended for human consumption may only be slaughtered from 24 hours after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinfectives and antiseptics for intra-uterine use, antibacterials.
ATC vet code: QG51AA05

5.1 Pharmacodynamic properties

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 Metricure, concentrations of cephapirin in endometrial tissue above the MIC of sensitive bacteria are maintained for at least 24 hours.

5.2 Pharmacokinetic particulars

After intra-uterine 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 intra-uterine administration of Metricure, high cephapirin concentrations are observed in the endometrium (10.4 µg/g at 8 hours after treatment).

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol cetostearyl ether-20
Macrogol cetostearyl ether-12
Hydrogenated castor oil
Triglycerides, medium chain

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
The product is a single use syringe.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and composition of immediate packaging

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
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8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/053/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st November 2006

10 DATE OF REVISION OF THE TEXT

November 2017