

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metricure 500 mg Intrauterine Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each syringe contains:

Cefapirin 500 mg
(as Cefapirin benzathine)

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intrauterine suspension.
Cream coloured homogenous suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cows

4.2 Indications for use, specifying the target species

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

4.3 Contra-indications

Do not administer to animals known to be allergic to cephalosporins or penicillins.

4.4 Special warning for each target species

None

4.5 Special precautions for use

i. Special precautions 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.

- ii. Special precautions to be taken by the person administering the medicinal product to the animals

Accidental spillage on the skin should be washed off immediately with soap and water.

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

1. Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.
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 with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

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 reaction(s) 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 or lactation

The product is not indicated for use during pregnancy but can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Not to be administered concurrently with other intra-uterine 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. 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 Metricure.

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, Metricure 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.

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

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

4.11 Withdrawal period(s)

Meat - 1 day

Milk - Zero hours

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QG51AA05

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

After intra-uterine 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 intra-uterine administration of Metricure, high cefapirin concentrations are observed in endometrium.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alcohol (C₁₆-C₁₈) 12 mole ethoxylate

Cetomagrocol 1000

Castor oil, hydrogenated

Coconut oil, fractionated

6.2 Incompatibilities

None known

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C. Syringes are for single use only. Keep syringe in outer carton.

6.5 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. Intra-uterine catheters are provided for administration.

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

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

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4099

9. DATE OF FIRST AUTHORISATION

14 October 2003

10. DATE OF REVISION OF TEXT

December 2024

Gavin Hall
Approved: 09 December 2024