

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metricure 500 mg Intrauterine Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 19 g syringe contains an oily suspension of 500 mg cefapirin (as cefapirin benzathine).

3. PHARMACEUTICAL FORM

Intrauterine suspension.

4. PACKAGE SIZE

This pack contains: 12 syringes

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For infusion in cattle for the treatment of subacute and chronic endometritis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intrauterine

8. WITHDRAWAL PERIOD

Withdrawal periods:

Meat - 1 day after last treatment

Milk - Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet for directions, disposal advice and warnings before use.
Penicillin/cephalosporins may occasionally cause severe allergic reactions.

See package leaflet for user warnings.

10. EXPIRY DATE

Expiry end of:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Syringes are for single use only.

Keep syringe in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read package leaflet for directions, disposal advice and warnings before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

FOR ANIMAL TREATMENT ONLY.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:

MSD Animal Health UK Ltd., Walton Manor, Walton, Milton Keynes, MK7 7AJ

Distributed in Northern Ireland by

INTERVET IRELAND Ltd. Magna Drive, Magna Business Park, Citywest Road,
Dublin 24

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4316

17. MANUFACTURER’S BATCH NUMBER

Batch No./Expiry end of:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS**

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metricure 500 mg Intrauterine Suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

19 g Contains 500 mg cefapirin (as cefapirin benzathine)

Oily suspension for the treatment of subacute and chronic endometritis.

Read package leaflet for directions, disposal advice and warnings before use.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

19 g

Syringes are for single use only. Do not store above 25°C.

Keep syringe in outer carton.

4. ROUTE(S) OF ADMINISTRATION

Intrauterine

5. WITHDRAWAL PERIOD

Withdrawal periods: Meat - 1 day after last treatment

Milk - Zero hours

6. BATCH NUMBER

Batch No.:

7. EXPIRY DATE

EXP end of:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only. Keep out of reach and sight of children.

MA Holder: MSD Animal Health UK Ltd., Walton Manor, Walton, Milton Keynes,
MK7 7AJ

Distributed in Northern Ireland by: INTERVET IRELAND Ltd, Magna Drive,
Magna Business Park, Citywest Road, Dublin 24

POM-V

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[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND
OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR
BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:

Intervet International BV
PO Box 31
5830 AA Boxmeer
Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metricure 500 mg Intrauterine Suspension

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Syringe containing a suspension of 500 mg cefapirin (as Cefapirin benzathine) in an oily base.

4. INDICATION(S)

Cefapirin, a first generation cephalosporin, is a broad spectrum antibiotic with bactericidal action against grampositive and gram-negative bacteria.

Cefapirin is resistant to the action of penicillinase.

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.

5. CONTRAINDICATIONS

The product should not be administered to animals known to be allergic to cephalosporins or penicillins.

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

The product should not be used concurrently with other intrauterine antibiotic preparations.

6. ADVERSE REACTIONS

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).

7. TARGET SPECIES

Cows

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

1. Shake syringe before use.
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.

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

See 8.

10. WITHDRAWAL PERIOD(S)

Meat - 1 day after last treatment

Milk - Zero hours

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Syringes are for single use only.

Keep syringe in outer carton.

12. SPECIAL WARNING(S)

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.

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 sensitivity and 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.

FOR ANIMAL TREATMENT ONLY.

KEEP OUT OF REACH AND SIGHT OF CHILDREN

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2021

15. OTHER INFORMATION

POM-V

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Vm 01708/4316

PACKAGE QUANTITIES

Packs containing 12 syringes. Intra-uterine catheters are also provided for administration.

Approved: 28/04/21

