LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEFSHOT DC 250mg Intramammary Suspension for Cattle

Cefalonium (as cefalonium dihydrate)

2. STATEMENT OF ACTIVE SUBSTANCES

Each 3 g intramammary syringe contains:

Active substance:
Cefalonium 250mg (as cefalonium dihydrate)

3. PHARMACEUTICAL FORM

Intramammary Suspension.

4. PACKAGE SIZE

24 or 120 intramammary syringe and cleaning towels.

5. TARGET SPECIES

Cattle (dry cow)

6. INDICATION(S)

For the treatment of subclinical mastitis at drying-off and the prevention of new bacterial infections of the udder during the non-lactating period of cows caused by *Staphylococcus aureus, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus uberis, Trueperella pyogenes, Escherichia coli* and *Klebsiella* spp

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Meat and offal:
21 days

Milk:
- 96 hours after calving if the dry period is higher than 54 days
- 58 days following the treatment if the dry period is below or equal to 54 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

Do not freeze.

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

Dispose of waste material in accordance with local requirements.

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

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4183

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

POLYETHYLENE SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEFSHOT DC 250mg Intramammary Suspension for Cattle

Cefalonium (as cefalonium dihydrate)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Cefalonium 250mg (as cefalonium dihydrate)

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

3 g

4. ROUTE(S) OF ADMINISTRATION

For intramammary use.

5. WITHDRAWAL PERIOD(S)

Meat and offal:
21 days

Milk:
- 96 hours after calving if the dry period is higher than 54 days
- 58 days following the treatment if the dry period is below or equal to 54 days.

Read the package leaflet before use.

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

<EXP {month/year}>

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
CEFSHOT DC 250mg Intramammary Suspension for Cattle

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

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Cross Vet Pharm Group, Ltd.
Broomhill Road
Tallaght
Dublin 24
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEFSHOT DRY COW 250mg Intramammary Suspension for Cattle

Cefalonium (as cefalonium dihydrate)

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

Each 3 g intramammary syringe contains:
Active substance:
Cefalonium 250mg (as cefalonium dihydrate)
Off-white to brownish suspension.

4. INDICATION(S)

For the treatment of subclinical mastitis at drying-off and the prevention of new bacterial infections of the udder during the non-lactating period of cows caused by *Staphylococcus aureus, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus uberis, Trueperella pyogenes, Escherichia coli* and *Klebsiella* spp..

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to cephalosporins, other β-lactam antibiotics or to any of the excipients.

6. ADVERSE REACTIONS

In very rare cases immediate hypersensitivity reactions were observed in some animals (restlessness, tremors, swelling of mammary gland, eyelids and lips). These reactions can lead to death.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (dry cow)

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

For intramammary use.

A single administration corresponding to the contents of one syringe (250 mg cefalonium) should be infused into the teat canal of each quarter immediately after the last milking of the lactation.
After milking is complete thoroughly clean and disinfect the end of the teat with the teat wipes cleaning towel provided. Remove the cap fully by holding the barrel of the syringe firmly in one hand and with the thumb and push up along the length of the cap until the cap clicks off. Take care not to contaminate the nozzle. Do not bend the nozzle.

Insert the nozzle into the teat canal and apply steady pressure on the syringe plunger until the full dose has been delivered. Holding the end of the teat with one hand, gently massage upwards with the other to aid dispersion of the antibiotic into the quarter. After infusion it is advisable to dip the teats in an antiseptic preparation specifically designed for this purpose.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Meat and offal:
21 days

Milk:
- 96 hours after calving if the dry period is higher than 54 days
- 58 days following the treatment if the dry period is below or equal to 54 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton or bucket and on the syringe after “EXP”. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:

None.

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.
Use of the product should be in accordance with official, national and regional antimicrobial policies.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the cefalonium and may decrease the effectiveness of treatment with other beta lactams.

The feeding of waste milk containing residues of cefalonium to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

The efficacy of the product is only established against the pathogens mentioned in section 4.2 “Indications for use”. Consequently, serious acute mastitis (potentially fatal) due to other pathogen species, mainly *Pseudomonas aeruginosa*, can occur after the drying off. Good hygienic practices should be thoroughly respected in order to reduce that risk; cows should be housed in a hygienic paddock far from the milking parlour and regularly checked several days after drying off.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.
Penicillin 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 may occasionally be serious.

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

Lactation:
Do not use during lactation.

Interaction with other medicinal products and other forms of interaction:

Cephalosporins should not be administered concurrently with bacteriostatic antimicrobials. Concomitant use of cephalosporins and nephrotoxic drugs may increase renal toxicity.

Overdose (symptoms, emergency procedures, antidotes):
Not applicable.

Incompatibilities:
None known.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

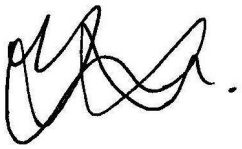
June 2020

15. OTHER INFORMATION

Pack sizes:
24 intramammary syringes in a carton.
120 intramammary syringes in a bucket.
All pack sizes contain cleaning towels.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.



Approved: 22 September 2020