PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Vial label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Excenel™ 50 mg/ml Sterile Powder for Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each vial contains ceftiofur sodium equivalent to 1 g ceftiofur, to be reconstituted with 20 ml of Water for Injection.

Each vial contains ceftiofur sodium equivalent to 4 g ceftiofur, to be reconstituted with 80 ml of Water for Injection.

Each ml of reconstituted solution contains: Ceftiofur sodium equivalent to 50 mg ceftiofur.

3. PHARMACEUTICAL FORM

Sterile Powder for Solution for Injection

4. PACKAGE SIZE

1 g
4 g

5. TARGET SPECIES

Cattle, pigs, horses [as animal icons]

6. INDICATION(S)

Information for use: see package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use in cattle, pigs and horses.

8. WITHDRAWAL PERIOD

Cattle (meat): 1 day. Cattle (milk): zero hours.

Pigs (meat): 2 days.

Not for use in horses intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

See package leaflet for full details.

CONTRA-INDICATIONS, WARNINGS ETC: Contra-indicated in animals previously found to be hypersensitive to ceftiofur.Operator warnings: Penicillins/cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full user and other warnings/precautions.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Protect from light. Store unreconstituted product in a refrigerator (+2°C to +8°C). After reconstitution, product may be stored for 7 days at +2°C to +8°C, or for 12 hours when stored below 25°C.

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

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

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

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

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

Keep out of 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

Vm 42058/5169

17. MANUFACTURER'S BATCH NUMBER

LOT:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Excenel™ 50 mg/ml Sterile Powder for Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each vial contains ceftiofur sodium equivalent to 1 g ceftiofur.

Each vial contains ceftiofur sodium equivalent to 4 g ceftiofur.

Each ml of reconstituted solution contains: Ceftiofur sodium equivalent to 50 mg ceftiofur.

3. PHARMACEUTICAL FORM

Sterile Powder for Solution for Injection

4. PACKAGE SIZE

1 g
4 g

5. TARGET SPECIES

Cattle, pigs, horses [as animal icons]

6. INDICATION(S)

Antibiotic.

Uses: For the treatment of bacterial respiratory disease in cattle, pigs and horses.

For the treatment of foul in the foot in cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use in cattle, pigs and horses.

Directions for use: see package leaflet.

8. WITHDRAWAL PERIOD

Withdrawal periods:

Cattle (meat): 1 day. Cattle (milk): zero hours.

Pigs (meat): 2 days.

Not for use in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

CONTRA-INDICATIONS, WARNINGS ETC: Contra-indicated in animals previously found to be hypersensitive to ceftiofur.

Operator warnings: Penicillins/cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full user and other warnings/precautions.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Protect from light. Keep the vial stored in this outer carton.

Store unreconstituted product in a refrigerator (+2°C to +8°C). After reconstitution, product may be stored for 7 days at +2°C to +8°C, or for 12 hours when stored below 25°C.

Discard date:

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

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

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

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

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

Keep out of 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

Vm 42058/5169

17. MANUFACTURER'S BATCH NUMBER

LOT:

PACKAGE LEAFLET FOR:

Excenel 50 mg/ml Sterile Powder for Solution for Injection

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
Site of batch release not currently stated

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Excenel™ 50 mg/ml Sterile Powder for Solution for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each vial contains ceftiofur sodium, equivalent to 1 g or 4 g ceftiofur.

The colour of the powder may vary from off-white to tan. Colour does not affect potency.

Each ml of reconstituted solution contains:

Ceftiofur sodium equivalent to 50 mg ceftiofur.

4. INDICATIONS

Excenel contains ceftiofur which is a beta-lactamase resistant, broad spectrum, bactericidal cephalosporin antibiotic. The product is indicated for:

1) The treatment of cattle with acute respiratory disease in which *Mannheimia haemolytica*, *Pasteurella multocida*, *Actinobacillus* (*Haemophilus*) *somnus* or other sensitive bacterial pathogens of the respiratory tract are involved.

2) The treatment of cattle with acute interdigital necrobacillosis (foul in the foot) in which *Fusobacterium necrophorum* and *Bacteroides melaninogenicus* are involved.

As with all antibiotic therapy, treatment of this condition with Excenel should be instituted as early as possible in order to provide maximum clinical effect.

3) The treatment of pigs with bacterial respiratory disease in which *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and/or *Streptococcus suis* are involved.

4) The treatment of horses with bacterial respiratory disease in which Streptococcus spp. (including *Streptococcus zooepidemicus* and *Streptococcus equi*), Staphylococcus spp. and/or Pasteurella spp. are involved.

5. CONTRAINDICATIONS

The use of Excenel is contra-indicated in animals previously found to be hypersensitive to ceftiofur.

Do not use in poultry (including eggs) due to the risk of spread of antimicrobial resistance to humans.

The administration of antimicrobials to horses under conditions of stress may be associated with acute diarrhoea which could be fatal. If acute diarrhoea is observed, discontinue use of this antimicrobial and initiate appropriate corrective therapy.

6. ADVERSE REACTIONS

The use of Excenel may cause occasional local discomfort upon injection but this is a transient effect.

7. TARGET SPECIES

Cattle, pigs and horses.

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

The intramuscular route only should be used in cattle, pigs and horses. In the pig, particular care must be taken to avoid injection into fat tissue.

Cattle: 1 mg/kg bodyweight. This is equivalent to 1 ml of the reconstituted solution per 50 kg bodyweight. For respiratory disease, the dose should be given once daily at 24 hour intervals for 3 to 5 days in total. For interdigital necrobacillosis (foul in the foot), the dose should be given once daily at 24 hour intervals for 3 days in total.

Pigs: 3 mg/kg bodyweight. This is equivalent to 1 ml of the reconstituted solution per 16 kg bodyweight. The dose should be given once daily at 24 hour intervals for 3 days in total. If no response is seen within these periods, the diagnosis should be redetermined.

Horses: 2 mg/kg bodyweight. This is equivalent to 2 ml of the reconstituted solution per 50 kg bodyweight. The dose should be given once daily at 24 hour intervals and continued for 48 hours after clinical signs have disappeared. A 10 day treatment period is usually adequate. A maximum of 10 ml solution should be administered per injection site. If no response is seen within 4-5 days, the diagnosis should be redetermined.

9. ADVICE ON CORRECT ADMINISTRATION

Reconstitution:

1 g vial - Reconstitute by adding 20 ml Water for Injection.

4 g vial - Reconstitute by adding 80 ml Water for Injection.

For ease of reconstitution, use an 18 gauge needle. Rapid addition of diluent will give best results.

Normal aseptic injection techniques should be practised.

10. WITHDRAWAL PERIOD)

Cattle: meat: 1 day.
milk: zero hours.

Pigs: meat: 2 days.

Horses: Do not use in horses intended for human consumption.

Treated horses may never be slaughtered for human consumption.

The horse must be declared as not intended for human consumption under national horse passport legislation.

11. SPECIAL STORAGE PRECAUTIONS

Protect from light.

Store unreconstituted product in a refrigerator (store between +2°C and +8°C). After reconstitution, product may be stored for 7 days at +2°C to +8°C, or for 12 hours when stored below 25°C.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided on the carton.

12. SPECIAL WARNING(S)

Use of Excenel Sterile Powder may constitute a risk to public health due to the spread of antimicrobial resistance.

Excenel Sterile Powder should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly to first line treatment.

Official, national and regional antimicrobial policies should be taken into account when the product is used. Increased use, including use of the product deviating from

the instructions given, may increase the prevalence of such resistance. Whenever possible, Excenel Sterile Powder should only be used based on susceptibility testing.

User Warnings: Care should be taken to avoid accidental self-injection. In the event of accidental self-injection, seek medical advice immediately. 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 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 and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention. Wash hands after use.

Keep out of reach and sight of children.

For animal treatment only

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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

15. OTHER INFORMATION

After recommended dose, therapeutic levels of ceftiofur are achieved within a few minutes and are maintained for at least 24 hours.

Excenel Sterile Powder is supplied as 1 g vials and 4 g vials. Not all pack sizes may be marketed.

POM-V

To be supplied only on veterinary prescription.

Vm 42058/5169

Gavin Hall

Approved 15 November 2024