SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Excenel 50 mg/ml sterile powder for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains:

Active substance:
Ceftiofur (as ceftiofur sodium) 1 g
Ceftiofur (as ceftiofur sodium) 4 g

Each ml of reconstituted product contains:

Active substance:
Ceftiofur 50 mg

Excipients:

Qualitative composition of excipients and other constituents
Potassium dihydrogen phosphate
Sodium hydroxide solution, 10% (for pH adjustment)

Powder: A white to light brown freeze-dried solid.
Reconstituted product: A clear, brownish-yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs, and horses.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for treatment of bovine bacterial respiratory disease associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Actinobacillus (Haemophilus) somnus* and other sensitive bacterial pathogens.

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

The treatment of pigs with bacterial respiratory disease in which *Actinobacillus (Haemophilus) pleuropneumonia*, *Pasteurella multocida* and *Streptococcus suis* are involved.

For the treatment of horses with bacterial respiratory disease associated with *Streptococcus* spp. (including *Streptococcus zooepidemicus*), *Staphylococcus* spp. and/or *Pasteurella* spp.

3.3 Contraindications

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

3.4 Special warnings

Use of the veterinary medicinal product may constitute a risk to public health due to the spread of antimicrobial resistance.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 therapy.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle, pigs, and horses:

Very common (>1 animal / 10 animals treated):	Injection site pain[1]

[1] Temporary; this reaction was associated with a transient increase in muscle enzymes

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
The safety of the veterinary medicinal product has not been established during pregnancy.
Laboratory studies in rats have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramuscular use in cattle, pigs, and horses.

Reconstitution:
Dissolve the 1 g sterile powder in 20 ml of water for injections.
Dissolve the 4 g sterile powder in 80 ml of water for injections.

Rapid addition of diluent will give best results.

The resulting solution contains 50 mg ceftiofur free acid equivalents per ml. For ease of reconstitution use an 18-gauge needle.

Dosage

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. As with all antibiotic therapy, treatment of this condition with the veterinary medicinal product should be instituted as early as possible in order to provide maximum clinical benefit.

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.

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 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 re-determined.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None known.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

The veterinary medicinal product selects for resistant strains such as bacteria carrying extended spectrum beta-lactamases (ESBL) and may constitute a risk to human health if these strains disseminate to humans e.g. via food. For this reason, the veterinary medicinal product should be reserved for the treatment of clinical conditions which have responded poorly or are expected to respond poorly (refers to very acute cases when treatment must be initiated without bacteriological diagnosis) 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 in the SPC, may increase the prevalence of such resistance. Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing.

The veterinary medicinal product is intended for treatment of individual animals. Do not use for disease prevention or as a part of heard health programmes. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.

3.12 Withdrawal periods

Meat and offal:
Cattle: 1 day.
Pigs: 2 days.
Milk:
Cattle: Zero hours.

Not authorised 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01DD90

Third-generation cephalosporins.

The veterinary medicinal product contains sodium ceftiofur, a broad-spectrum cephalosporin which is active against Gram-positive and Gram-negative bacteria, including beta-lactamase producing strains.

Ceftiofur has bactericidal activity in vitro. The mode of action is that of cephalosporins, i.e. inhibition of the bacteria cell wall synthesis.

After intramuscular administration ceftiofur is quickly metabolized to desfuroylceftiofur which reaches its maximum plasma concentration within 1 hour. The half-life of desfuroylceftiofur is on average greater than 9 hours in cattle and 13 hours in pigs. No accumulation has been shown after several administrations.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: 7 days (when stored at 2 °C - 8 °C) or 12 hours (when stored below 25 °C).

5.3 Special precautions for storage

Store in a refrigerator (2 °C - 8 °C).
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Cardboard carton containing one colourless type I glass vial of 1 g or 4 g, closed with a butyl rubber stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 42058/5169

8. DATE OF FIRST AUTHORISATION

30 December 1996

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

December 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 27 May 2026