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 bottle contains ceftiofur (as sodium ceftiofur) 1 g or 4 g.
Each ml of reconstituted solution contains ceftiofur 50 mg.

For a full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Powder for solution for injection.
Sterile white to beige freeze-dried amorphous powder for aqueous reconstitution and parenteral administration to animals.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, pigs and horses.

4.2 Indications for use, specifying the target species

Ceftiofur sodium (Excenel) 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.

4.3 Contraindications

As for all antibiotics, do not administer to animals previously found to be hypersensitive to the active ingredient.
Do not use in poultry (including eggs) due to the risk of spread of antimicrobial resistance to humans.

4.4 Special warnings for each 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.

4.5 Special precautions for use

i. Special precautions for use in animals

Excenel Sterile Powder selects for resistant strains such as bacteria carrying extended spectrum betalactamases (ESBL) and may constitute a risk to human health if these strains disseminate to humans e.g. via food. For this reason, Excenel Sterile Powder 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, Excenel Sterile Powder should only be used based on susceptibility testing.

Excenel Sterile Powder 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.

i. 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 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.

4.6 Adverse reactions (frequency and seriousness)

General symptoms are not detected. The use of ceftiofur sodium may result in some signs of immediate and short lasting pain at the site of injection.

4.7 Use during pregnancy, lactation or lay

No data available for cattle.

In rats no teratogenic signs, abortion or influence on reproduction have been observed.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Dissolve the 1 g sterile powder in 20 ml of Water for Injection.
Dissolve the 4 g sterile powder in 80 ml of Water for Injection

Rapid addition of diluent will give best results.

The resulting solution contains 50 mg ceftiofur free acid equivalents per ml. The reconstituted product is to be administered intramuscularly. 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 Excenel 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.

Administration
The intramuscular route only should be used in cattle, pigs and horses.

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

None known.

4.11 Withdrawal period(s)

Meat:
Cattle - 1 day
Pigs - 2 days

Milk:
Cattle - zero hours
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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: third generation cephalosporins

ATCVet code: QJ01DD90

Excenel Sterile Powder 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium Acid Phosphate
Sodium Hydroxide Solution 10% (for pH adjustment)

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Store unreconstituted product in a refrigerator (+2°C and +8°C).

After reconstituted, product may be stored for 7 days at +2°C and +8°C, or for 12 hours when stored below 25°C.

Protect from light.

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

6.5 Nature and composition of immediate packaging

Cardboard carton containing one Type 1 glass vial containing 1 g or 4 g of product, closed with a butyl rubber closure and aluminium cap.

Not all pack sizes may be marketed.

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

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

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4066

9. DATE OF THE FIRST AUTHORISATION

30 December 1996

10. DATE OF REVISION OF THE TEXT

August 2020

Approved 28 August 2020