Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Excenel 1 g Sterile Powder for Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains :

Active Substance:

Ceftiofur (as cetiofur sodium)	1.06g

When reconstituted with 20 ml water for injection, each ml of reconstituted solution contains ceftiofur 50mg.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for solution for injection.

A white to light brown freeze dried powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Pigs

4.2 Indications for use, specifying the target species

1. Ceftiofur sodium (Excenel) is indicated for treatment of bovine bacterial respiratory disease associated with *Pasteurella hemolytica, Pasteurella multocida,* and *Actinobacillus (Haemophilus) somnus.*

2. For the treatment of cattle with acute interdigital necrobacillosis (Foul in the Foot) in which *Fusobacterium necrophorum* and *Bacteroides melaninogenicus* are involved.

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

4.3 Contraindications

Do not administer to animals previously found to be hypersensitive to the active ingredient.

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

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

Special precautions for use in animals

Ceftiofur can cause minor irritation to damaged skin, in particular after frequent contact.
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 herd health programmes. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Ceftiofur can cause minor irritation to damaged skin, in particular after frequent contact.
Antimicrobial drugs including penicillin and cephalosporins can cause allergic reactions in sensitised individuals. To minimise the possibility of reactions, users of such products including ceftiofur are advised to avoid direct contact of the product with the skin and mucous membranes

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 a short lasting pain at the site of injection.

4.7 Use during pregnancy, lactation or lay

Pregnancy: no data are available for cattle or pigs. In the rat, no teratogenic signs, abortion or influence on reproduction have been observed.

Lactation: no restriction.

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 sterile powder in 20 ml 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.

Administration:

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

To ensure a correct dosage, bodyweight should be determined as accurately as possible.

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

Doses of more than 20 times the recommended dose given IM for 15 days and of more than 50 times the recommended dose during 5 days were well tolerated by calves.
In pigs, doses of 8.3 times the recommended dose IM for 15 days and of 42 times the recommended dose IM for 5 days were well tolerated.

4.11 Withdrawal Period(s)

Meat and offal:
Cattle: 24 hours
Pigs: 48 hours
Milk: Zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, third-generation cephalosporins
ATCvet Code: QJ01DD90

5.1 Pharmacodynamic properties

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 bacteria cell wall synthesis.

5.2 Pharmacokinetic properties

After intramuscular administration ceftiofur is quickly metabolised to desfuroylceftiofur which reaches its maximum plasma concentration within one 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 dihydrogen phosphate
Sodium hydroxide

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf-life after reconstitution according to directions: 24 hours.

6.4 Special precautions for storage

Store in a refrigerator (2ºC - 8ºC).

Protect from light.

6.5 Nature and composition of immediate packaging

Colourless flint glass (Type 1) 1g vial with butyl rubber stopper and aluminium overseal, containing a sterile white to light brown freeze dried cake for reconstitution with 20ml Water for Injections. Each vial is contained in a cardboard carton.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/052/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1988
Date of last renewal: 30th September 2008

10 DATE OF REVISION OF THE TEXT

May 2012
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