PIG HEALTH TODAY®
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discoveries

15 seconds

- **Pigs with swine respiratory disease due to *Actinobacillus pleuropneumoniae* were treated with Excede® for Swine (ceftiofur crystalline-free acid) or enrofloxacin in a comparative challenge study.**
- **Mortality and total lung lesion scores were significantly lower ($P \leq 0.05$) in the Excede for Swine versus the enrofloxacin groups.**
- **Pigs treated with Excede for Swine also had significantly less growth of *Streptococcus suis* compared to those treated with enrofloxacin.**

Pigs with APP have less mortality, fewer lung lesions after treatment with Excede® for Swine compared to enrofloxacin

Pigs with swine respiratory disease (SRD) due to *Actinobacillus pleuropneumoniae* (APP) had significantly less mortality and fewer lung lesions when they were treated with Excede® for Swine (ceftiofur crystalline free acid) compared to pigs treated with enrofloxacin, a comparative challenge study demonstrated.[1]

Excede for Swine also provided better protection against secondary infections with *Streptococcus suis* compared to enrofloxacin.

For the study, 140 healthy commercial pigs were randomly assigned to one of seven treatment groups, each with 20 pigs (Table 1). Three of the treatment groups received one dose of Excede for Swine at either 3, 5 or 7 days before an intratracheal challenge with APP serotype 5, a strain that remains common in the US.[2] Another three treatment groups received one dose of enrofloxacin at either 3, 5 or 7 days before the same challenge.

continued

Table 1. Study design

Treatment groups	Days before challenge treatments were administered	Number of pigs in each treatment group	Challenge (Day 0)	Study ends 5 days after challenge
Excede for Swine	-3	20	APP serotype 5	Pigs scored for lung lesions
Excede for Swine	-5	20		
Excede for Swine	-7	20		
Enrofloxacin	-3	20		
Enrofloxacin	-5	20		
Enrofloxacin	-7	20		
Saline	-3	20		
		140 Total		

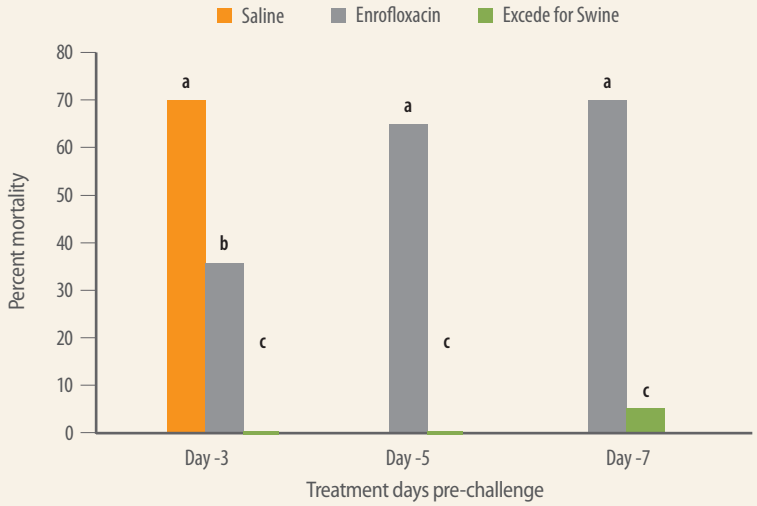
Sponsored by zoetis

Pigs with APP have less mortality, fewer lung lesions after treatment with Excede® for Swine compared to enrofloxacin

EVA JABLONSKI, DVM
ZOETIS

"Every group treated with Excede for Swine had less mortality compared to pigs treated with enrofloxacin (Figure 1) and the difference was significant ($P \leq 0.05$)."

Figure 1. Mortality in pigs challenged with APP serotype 5 following treatment with Excede for Swine or enrofloxacin



Note: Values with the same letter grouping within a column are not significantly ($P \leq 0.05$) different.

The seventh group received saline 3 days before challenge to provide a control. Excede for Swine and enrofloxacin were administered according to label directions.

"Every group treated with Excede for Swine had less mortality compared to pigs treated with enrofloxacin (Figure 1) and the difference was significant ($P \leq 0.05$)," reports Eva Jablonski, DVM, senior technical services veterinarian, Zoetis.

Lung lesion scores 5 days after challenge were based on the percent of gross lung involvement, she says. "The findings here too showed that every group treated with Excede for Swine had significantly ($P \leq 0.05$) lower total lung lesion scores compared to enrofloxacin-treated pigs," she says (Figure 2).[3]

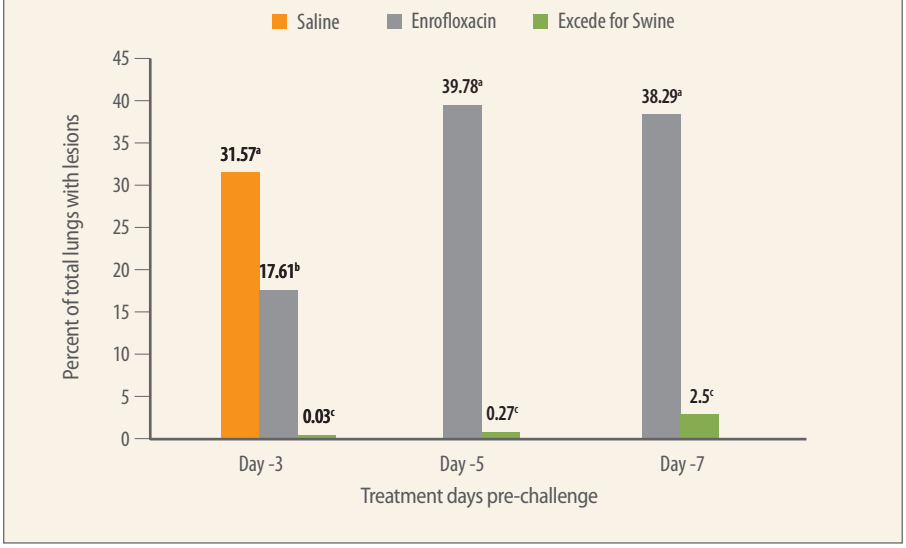
"Excede for Swine was more effective for a longer period against APP compared to enrofloxacin. Even though both are broad-spectrum antibiotics, enrofloxacin provided only limited or no protection for 3 days. The ability of Excede for Swine to prevent losses for longer can amount to substantial savings for producers," Jablonski says.

Protection against *S. suis*

As part of the same study, investigators evaluated protection against bacterial growth with APP as well as *S. suis*, which often occurs as a secondary infection to APP. The assessment was based on 65 APP and 63 *S. suis* isolates isolated from challenged pigs.

Excede for Swine provided superior protection against both APP and *S. suis* compared to enrofloxacin in the study (Figure 3), she says.

Figure 2. Lung lesion scores

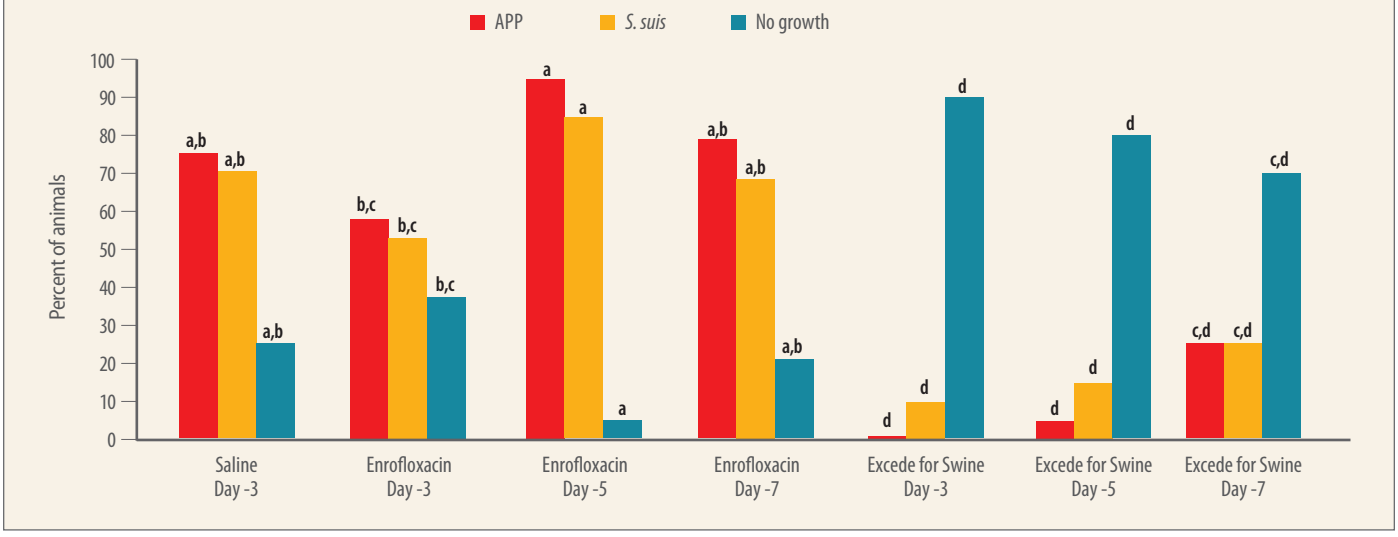


Note: Values with the same letters within a column are not significantly ($P \leq 0.05$) different.

Antimicrobial susceptibility testing conducted by Zoetis has demonstrated that APP and *S. suis* have remained highly susceptible to ceftiofur.

EVA JABLONSKI, DVM
ZOETIS

Figure 3. Bacterial isolations in pigs treated with Excede for Swine, enrofloxacin or saline in groups treated 3, 5 and 7 days before challenge



Note: The same letters within a column are not significantly ($P \leq 0.05$) different.

continued

Pigs with APP have less mortality, fewer lung lesions after treatment with Excede® for Swine compared to enrofloxacin

> "By using an antibiotic that reduces the need for retreatments, producers will save on medication as well as labor costs. An effective antibiotic should also mimimize performance losses, and all that adds up to better producer profits."
>
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> **ZOETIS**

Excede for Swine's efficacy against *S. suis* as well as *Haemophilus parasuis* was also demonstrated in a recent study conducted in association with Iowa State University.[4] Compared to an autogenous vaccination program and no treatment, pigs on a 4,000-head sow farm treated at weaning with Excede for Swine required significantly ($P \leq 0.05$) fewer antibiotic treatments.

The authors of the study concluded that "By reducing the number of treatments post-weaning, [Excede for Swine] improved pig health, decreased the labor associated with individual pig treatments and supported the responsible use of antibiotics on this farm."

Excede for Swine is a third-generation cephalosporin approved for treatment or control of SRD associated with APP and *S. suis* as well as *Pasteurella multocida* and *H. parasuis*. Its unique, extended-release properties have also been demonstrated in a pharmacokinetic analysis, which showed that therapeutic plasma levels of ceftiofur and desfuroylceftiofur-related metabolites are reached within just 1 hour after administration and are maintained for at least 7 days.[5]

The Zoetis antimicrobial susceptibility testing program monitors the susceptibility of APP, *S. suis* and *P. multocida*. All three pathogens have remained highly susceptible to ceftiofur since it was launched over 15 years ago,[6] Jablonski says.

"By using an antibiotic that reduces the need for retreatments, producers will save on medication as well as labor costs. An effective antibiotic should also mimimize performance losses, and all that adds up to better producer profits," she says.

IMPORTANT SAFETY INFORMATION
People with known hypersensitivity to penicillin or cephalosporins should avoid exposure to EXCEDE FOR SWINE. Do not use in swine found to be hypersensitive to the product. Pre-slaughter withdrawal time is 14 days following the last dose.
See full Prescribing Information on page 6.

For more information, contact Dr. Jablonski (eva.jablonski@zoetis.com) or your Zoetis representative.

[1] Data on file, Study Report No. ORPORK 2030, Zoetis LLC.

[2] *Actinobacillus pleuropneumoniae* in swine. Iowa State University.

[3] Data on file, Study Report No. ORPORK 2030, Zoetis LLC.

[4] Finch M, et al. Evaluation of the efficacy of ceftiofur crystalline free acid versus autogenous vaccination for control of *Streptococcus suis* and *Haemophilus parasuis* in a commercial swine production system. Am Assoc Swine Vet. 2019.

[5] Hibbard B, et al. Pharmacokinetics of ceftiofur crystalline free acid in swine. Proceedings of the 18th IPVS Congress, Hamburg, Germany 2004, Volume 2.

[6] Sweeney M, et al. Antimicrobial susceptibility of *Actinobacillus pleuropneumoniae, Pasteurella multocida, Streptococcus suis,* and *Bordetella bronchiseptica* isolated from pigs in the United States and Canada, 2011 to 2015. J Swine Health Prod. 2017;25(3):106-120.

notes

EXCEDE® FOR SWINE

(Ceftiofur Crystalline Free Acid)

Sterile Suspension 100 mg/mL

For intramuscular administration in the post-auricular region of the neck of swine.

CAUTION

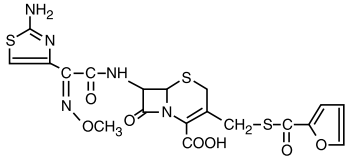
Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Federal Law prohibits extra-label use of this drug in swine for disease prevention purposes; at unapproved doses; frequencies, durations, or routes of administration; and in unapproved major food producing species/production classes.

DESCRIPTION

EXCEDE FOR SWINE Sterile Suspension 100 mg/mL is a ready-to-use formulation that contains the crystalline free acid of ceftiofur, which is a broad spectrum cephalosporin antibiotic active against gram-positive and gram-negative bacteria including ß-lactamase-producing strains. Like other cephalosporins, ceftiofur is bactericidal *in vitro*, resulting from inhibition of cell wall synthesis.

Each mL of this ready-to-use sterile suspension contains ceftiofur crystalline free acid equivalent to 100 mg ceftiofur, in a Miglyol® and cottonseed oil based suspension.

Figure 1. Structure of ceftiofur crystalline free acid:



Chemical name of ceftiofur crystalline free acid:
7-[[2-(2-Amino-4-thiazolyl)-2-(methoxyimino)acetyl]amino]-3-[[(2-furanylcarbonyl)thio]methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene 2-carboxylic acid

INDICATIONS

EXCEDE FOR SWINE Sterile Suspension 100 mg/mL is indicated for the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis,* and *Streptococcus suis;* and for the control of SRD associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis,* and *Streptococcus suis* in groups of pigs where SRD has been diagnosed.

DOSAGE

Administer by intramuscular (IM) injection in the post-auricular region of the neck as a single dosage of 2.27 mg ceftiofur equivalents (CE)/lb (5.0 mg CE/kg) body weight (BW). This is equivalent to 1 mL sterile suspension per 44 lb (20 kg) BW. No more than 2 mL should be injected in a single injection site. Injection volumes in excess of 2 mL per injection site may result in violative residues. Pigs heavier than 88 lb (40 kg) will require more than one injection.

Most animals will respond to treatment within three to five days. If no improvement is observed, the diagnosis should be re-evaluated.

ADMINISTRATION

Shake well before using. EXCEDE FOR SWINE Sterile Suspension 100 mg/mL is to be administered by intramuscular injection in the post-auricular region of the neck.

CONTRAINDICATIONS

As with all drugs, the use of EXCEDE FOR SWINE Sterile Suspension 100 mg/mL is contraindicated in animals previously found to be hypersensitive to the drug.

WARNINGS

FOR USE IN ANIMALS ONLY.
NOT FOR HUMAN USE. KEEP OUT OF REACH OF CHILDREN.

Penicillins and cephalosporins can cause allergic reactions in sensitized individuals. Topical exposures to such antimicrobials, including ceftiofur, may elicit mild to severe allergic reactions in some individuals. Repeated or prolonged exposure may lead to sensitization. Avoid direct contact of the product with the skin, eyes, mouth and clothing. Sensitization of the skin may be avoided by wearing protective gloves.

Persons with a known hypersensitivity to penicillin or cephalosporins should avoid exposure to this product.

In case of accidental eye exposure, flush with water for 15 minutes. In case of accidental skin exposure, wash with soap and water. Remove contaminated clothing. If allergic reaction occurs (e.g., skin rash, hives, difficult breathing), seek medical attention.

The material safety data sheet contains more detailed occupational safety information. To report adverse effects in users, to obtain more information or to obtain a material safety data sheet, call 1-888-963-8471.

RESIDUE WARNINGS

- A maximum of 2 mL of formulation should be injected at each injection site. Injection volumes in excess of 2 mL per injection site may result in violative residues.
- Following label use as a single treatment, a 14-day pre-slaughter withdrawal period is required.
- **Use of dosages in excess of 5.0 mg ceftiofur equivalents (CE)/kg or administration by an unapproved route may result in illegal residues in edible tissues.**

PRECAUTIONS

The safety of ceftiofur has not been demonstrated for pregnant swine or swine intended for breeding.

Administration of EXCEDE FOR SWINE Sterile Suspension 100 mg/mL as directed may induce a transient reaction at the site of injection and underlying tissues that may result in trim loss of edible tissue at slaughter.

ADVERSE REACTIONS

An injection site tolerance study demonstrated that EXCEDE FOR SWINE Sterile Suspension 100 mg/mL is well tolerated in pigs. Half of the injection sites at both 3 and 7 days post-injection were scored as "negative" for irritation and the other half were scored as "slight irritation". All gross observations and measurements of injection sites qualified the sites at 10 days post-injection as "negative" for irritation.

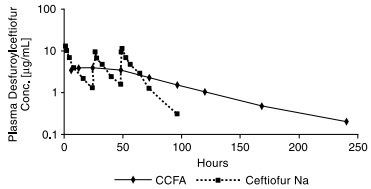
No adverse effects were observed in multi-location field efficacy studies involving more than 1000 pigs.

CLINICAL PHARMACOLOGY

Ceftiofur administered as either ceftiofur sodium (NAXCEL® Sterile Powder), ceftiofur hydrochloride (EXCENEL® RTU Sterile Suspension) or ceftiofur crystalline free acid (EXCEDE FOR SWINE Sterile Suspension 100 mg/mL) is metabolized rapidly to desfuroylceftiofur, the primary metabolite. Administration of ceftiofur to swine as ceftiofur crystalline free acid (CCFA) at a single IM dosage of 2.27 mg CE/lb (5.0 mg CE/kg) BW provides concentrations of ceftiofur and desfuroylceftiofurrelated metabolites in plasma that are multiples above the MIC_{90}* for the SRD label pathogens *Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis* and *Streptococcus suis* for an extended period of time (see Figure 2 and Tables 1–2).

The average plasma concentrations of ceftiofur- and desfuroylceftiofur-related metabolites for CCFA (EXCEDE FOR SWINE Sterile Suspension 100 mg/mL) after IM administration of 2.27 mg CE/lb (5.0 mg CE/kg) BW and those for ceftiofur sodium (NAXCEL Sterile Powder) after IM administration at 1.36 mg CE/lb (3 mg CE/kg) BW for three consecutive days are presented in Figure 2 below.

Figure 2. Average plasma concentrations of ceftiofur- and desfuroylceftiofur-related metabolites for CCFA (EXCEDE FOR SWINE Sterile Suspension 100 mg/mL) after IM administration of 2.27 mg CE/lb (5.0 mg CE/kg) BW and those for ceftiofur sodium (NAXCEL Sterile Powder) after IM administration at 1.36 mg CE/lb (3 mg CE/kg) BW for three consecutive days



Pharmacokinetic parameters measured after a single IM administration of 2.27 mg CE/lb (5.0 mg CE/kg) BW of EXCEDE FOR SWINE Sterile Suspension 100 mg/mL in the post-auricular region of the neck of swine are presented in the following table (Table 1).

* Minimum inhibitory concentration for 90% of the isolates

Table 1. Pharmacokinetic parameters in swine after a single IM administration of EXCEDE FOR SWINE Sterile Suspension 100 mg/mL at 2.27 mg CE/lb (5.0 mg CE/kg) BW

Pharmacokinetic Parameter	Mean Value ± Standard Deviation (non-compartmental analyses)
C_{max} (µg/mL)	4.17 ± 0.92
t_{max} (h)	22.0 ± 12.2
$AUC_{0\text{-}LOQ}$ (µg•h/mL)	373.0 ± 56.1
$t_{1/2}$ (h)	49.6 ± 11.8

C_{max} = maximum plasma concentration (in µg CE/mL)
t_{max} = the time after injection when C_{max} occurs (in hours)
$AUC_{0\text{-}LOQ}$ = the area under the plasma concentration vs. time curve from time of injection to the limit of quantitation of the assay (0.15 µg CE/mL)
$t_{1/2}$ = terminal phase biological half-life (in hours)

Table 2. Ceftiofur minimum inhibitory concentration (MIC) values* of indicated pathogens isolated from SRD treatment and control field studies conducted in the U.S.

Indicated Pathogens	Year(s) of Isolation	Field Study	Number of Isolates	MIC_{50}** (µg/mL)	MIC_{90}** (µg/mL)	MIC Range (µg/mL)
Actinobacillus pleuropneumoniae	2000 to 2001	Treatment	5	NA	NA	≤0.03 to 0.06
	2009	Control	34	0.03	0.06	0.015 to 0.06
Pasteurella multocida	2000 to 2001	Treatment	20	≤0.03	≤0.03	≤0.03†
	2009	Control	67	≤0.004	≤0.004	≤0.004†
Streptococcus suis	2000 to 2001	Treatment	30	0.06	0.12	≤0.03 to 0.5
	2009	Control	141	0.25	1	0.03 to >2

* The correlation between *in vitro* susceptibility data and clinical effectiveness is unknown.
** The lowest MIC to encompass 50% and 90% of the most susceptible isolates, respectively.
† No range; all isolates yielded the same value.

MICROBIOLOGY

Ceftiofur has demonstrated *in vitro* activity against *Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis,* and *Streptococcus suis,* four major pathogenic bacteria associated with SRD.

The minimum inhibitory concentrations (MICs) of ceftiofur against indicated SRD pathogens were determined using methods recommended by the Clinical and Laboratory Standards Institute (CLSI) using the M31-A and M31-A3 standards for the SRD treatment (2000-2001) and control (2009) studies, respectively. Isolates from the SRD treatment study were obtained from lung tissue collected from non-treated pigs prior to enrollment and saline-treated pigs that died or were euthanized during the study. Isolates from the SRD control study were obtained from lung tissue from non-treated pigs euthanized prior to enrollment and from saline- and ceftiofur-treated pigs that died or were euthanized during the study. The susceptibility results for the treatment and control studies are presented in Table 2.

Based on pharmacokinetic data from studies of ceftiofur in swine after a single intramuscular injection of 2.27 mg CE/lb (5.0 mg CE/kg) BW, the following interpretive criteria are recommended by CLSI:

Table 3. CLSI-accepted interpretive criteria for ceftiofur against swine respiratory disease pathogens*

Pathogens	Disk Potency	Zone Diameter (mm)	MIC (µg/mL)	Interpretation
Actinobacillus pleuropneumoniae	30 µg	≥21	≤2.0	(S) Susceptible
Pasteurella multocida		18-20	4.0	(I) Intermediate
Streptococcus suis		≤17	≥8.0	(R) Resistant

* These interpretive criteria should only be used when the CLSI M31-A3 performance standard is used to determine antimicrobial susceptibility to ceftiofur.

EFFECTIVENESS

The effectiveness of a single dose of 2.27 or 3.18 mg CE/lb BW (5.0 or 7.0 mg CE/kg BW) EXCEDE FOR SWINE Sterile Suspension 100 mg/mL for the treatment of SRD was confirmed in a well-controlled, multi-location field study. A total of 706 pigs with clinical signs of bacterial respiratory disease were enrolled and treated with a placebo injection or EXCEDE FOR SWINE Sterile Suspension 100 mg/mL administered as a single IM injection in the post-auricular region of the neck. Clinical observations were performed on Days 1-7 and rectal temperatures were taken on Days 1, 3, and 6 following treatment (Day 0). Necropsies were performed on all pigs that died during the study and after euthanasia of all remaining study pigs at the end of the 14-day post-enrollment study period. Lung lesions were scored and lungs were submitted for bacterial identification. Mortality rates were numerically lower (but not statistically different) for the EXCEDE FOR SWINE Sterile Suspension 100 mg/mL-treated groups (4.3% for the 5.0 mg CE/kg BW group and 4.2% for the 7.0 mg CE/kg BW group) compared with the placebo-treated control group (6.3%). There was a statistically significant ($p<0.05$) improvement in clinical cure rates for the EXCEDE FOR SWINE Sterile Suspension 100 mg/mL-treated groups (24.8% for the 5.0 mg CE/kg BW group and 26.4% for the 7.0 mg CE/kg BW group) compared with the placebo-treated control group (17.7%). Lung lesion scores were numerically higher (but not statistically different) for the EXCEDE FOR SWINE Sterile Suspension 100 mg/mL-treated groups (10.4% for both the 5.0 mg CE/kg BW and the 7.0 mg CE/kg BW group) compared with the placebo-treated control group (9.2%). Bacteriological culture of the lungs of study pigs identified the following respiratory pathogens: *Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis,* and *Streptococcus suis.*

The effectiveness of a single dose of 2.27 CE/lb BW (5.0 mg CE/kg BW) EXCEDE FOR SWINE for the control of SRD was evaluated in a multi-location natural infection field study. At each site, when at least 15% of the study candidates in a pen showed clinical signs of SRD, all pigs in the pen were enrolled and treated with EXCEDE FOR SWINE ($n = 346$) or saline ($n = 347$). Responses to treatment were evaluated 7 days post-treatment. Success was defined as a pig that survived to Day 7 and had normal attitude, normal respiration, and a rectal temperature of < 104 °F. The treatment success rate was significantly higher ($p = 0.0188$) for EXCEDE FOR SWINE-treated pigs (59.6%) compared to the saline-treated pigs (41.4%). Bacteriological culture of the lungs of study pigs identified the following respiratory pathogens: *Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis,* and *Streptococcus suis.*

Table 4. Acceptable quality control ranges for ceftiofur against CLSI recommended American Type Culture Collection (ATCC) reference strains

Organism Name (ATCC No.)	MIC (µg/mL)	Zone Diameter, mm (Disk Content 30 µg)
E. coli ATCC 25922	0.25–1.0	26–31
S. aureus ATCC 29213	0.25–1.0	—
S. aureus ATCC 25923	—	27–31
P. aeruginosa ATCC 27853	16.0–64.0	14–18

ANIMAL SAFETY

After parenteral administration, CCFA, ceftiofur sodium, and ceftiofur hydrochloride are metabolized to the same principal metabolite, desfuroylceftiofur. Plasma levels achieved are similar after recommended dosing (Figure 2). Therefore, studies conducted with ceftiofur sodium are adequate to evaluate the systemic safety of CCFA. Results from a five-day tolerance study in normal feeder pigs indicated that ceftiofur sodium produced no overt adverse signs of toxicity and was well tolerated when administered at 57 mg CE/lb (125 mg/kg) BW (more than 25 times the recommended dosage of CCFA) for five consecutive days. An additional dose toxicity study was conducted to determine the safety margin of ceftiofur in swine. Five barrows and five gilts per group were administered ceftiofur sodium IM at 0, 2.27, 6.81 and 11.36 mg CE/lb (0, 5, 15, 25 mg CE/kg) BW (0, 1, 3 and 5 times the recommended dosage for CCFA) for 15 consecutive days. There were no adverse systemic effects observed, indicating that ceftiofur sodium has a wide margin of safety when administered intramuscularly in feeder pigs.

A separate study evaluated the injection site tissue tolerance of EXCEDE FOR SWINE Sterile Suspension 100 mg/mL in swine when administered intramuscularly as a single injection at the maximum recommended dose volume of 2 mL (approximately 5 mg CE/kg BW) per injection site. Because injection site volumes greater than 2 mL may result in violative residues, only injection volumes of 2 mL were evaluated in this study. EXCEDE FOR SWINE Sterile Suspension 100 mg/mL was injected intramuscularly into each side of the neck of six swine at a dose volume of 2 mL/injection site. Clinical observations were made daily. At 3, 7 and 10 days post-injection, pairs of animals were euthanized and the neck injection sites were dissected for pathological examination (4 injection sites per time point). The injections were well tolerated in all pigs. Clinically, injection site reactions ranged from nondetectable (6 of 12 sites) to a transitory (up to 4 days post-injection) palpable, nonvisible swelling (2 of 12 sites) or a small, visible, reddened nodule at the needle insertion point (4 of 12 sites; 3 of 4 nodules were barely detectable by 3 to 7 days post-injection). There was no clinical evidence of the injections at 10 days post-injection. At necropsy, half of the injection sites at both 3 and 7 days post-injection were scored as "negative" for irritation and the other half were scored as "slight irritation". One animal had a visible lesion described as an area of tan with red speckles present in the deep muscle fascia, less than 6 cm^2, at 10 days post-injection; this lesion and the remaining injection sites evaluated at 10 days post-injection were scored as "negative" for irritation.

STORAGE CONDITIONS

Store at controlled room temperature 20° to 25°C (68° to 77°F). Shake well before using. Contents should be used within 12 weeks after the first dose is removed.

HOW SUPPLIED

EXCEDE FOR SWINE Sterile Suspension 100 mg/mL is available in the following package size:
100 mL vial

NADA #141-235, Approved by FDA

zoetis

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

www.excede.com or call
1-888-963-8471

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