THE FACTS ABOUT CEFTIOFUR: ANTIBIOTIC STEWARDSHIP AND SAFETY

Ceftiofur is a cephalosporin antibiotic approved by the U.S. Food and Drug Administration (FDA) for treatment of serious diseases in food animals.† The FDA's approval means that veterinarians can be assured that proper product use will help resolve diagnosed diseases while also protecting the safety of the food supply.

TARGETED — PRESCRIPTION-ONLY — USE FOR INDIVIDUAL ANIMAL TREATMENT

Ceftiofur is only available by veterinarian prescription. Veterinarians may prescribe ceftiofur products for specific uses that are approved by the FDA. These approved uses are for the treatment of:

- Respiratory disease in cattle, swine, sheep, goats and horses
- Foot rot in cattle
- Acute postpartum metritis in cattle
- Clinical mastitis in lactating dairy cattle
- Existing infections at the time of dry cow therapy in dry dairy cattle

Veterinarians also may prescribe ceftiofur products to help control disease after it has been diagnosed within a group. Ceftiofur is approved to help control:

- Early mortality associated with *Escherichia coli (E.coli)* in day-old chicks and turkey poults
- Respiratory disease in swine
- Respiratory disease in cattle

The FDA, as directed on the product label, has very specific uses for ceftiofur in food-producing animals:

- Available only through veterinary prescription
- Only used for specific serious animal diseases
- Proper dose and duration of therapy instructions
- Administered to individual animals only as an injectable or infusion treatment
- Not available as a feed or water additive
- No approved uses for preventing disease or for promoting growth
- Use of ceftiofur-containing products at unapproved doses, frequency, duration, routes of administration or into unapproved species is prohibited

Ceftiofur is only used in targeted instances to treat and control animal diseases. All cephalosporins represent less than 0.3% of all medically important antibiotics sold for use in animals.[1]

MULTIPLE FDA APPROVALS REINFORCE CEFTIOFUR'S SAFETY

Ceftiofur is one of the animal antibiotics most extensively evaluated by the FDA. The agency has reviewed data in support of the safety and effectiveness of ceftiofur, with the first approval in 1988. Since then, the agency has approved ceftiofur for use in farm animals more than 20 times to provide veterinarians with effective treatments for serious conditions in animals. The FDA's most recent approval of a ceftiofur formulation was in 2013, taking into account all relevant and published scientific research concerning microbial safety and food safety.

FOOD SAFETY CRITICAL TO APPROVAL OF CEFTIOFUR

The FDA's approval process for ceftiofur, or any antibiotic for food animals, hinges on whether food from the treated animal is safe for human consumption after the product has been used as directed. If ceftiofur didn't pass the FDA's food safety requirements, it would not have received approval initially or in subsequent evaluations for additional uses.

As part of the government's food safety monitoring umbrella, the U.S. Department of Agriculture (USDA) has a multitiered program to detect violative residues in the food supply, which includes "scheduled sampling" that is statistically designed to gain insights about the level of residues in animals going into the food chain. This program finds that the prevalence of antibiotic residue violations across the meat supply is very low, and ceftiofur has not been identified among the antibiotic medicines with the greatest frequency of drug residues.[2]

Zoetis supports on-label use of its ceftiofur products through our Residue Free Guarantee.™* This backing reinforces to our customers that using these products according to label directions is not associated with drug residue violations in milk or meat.

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As part of the FDA approval process and, more especially, the human food safety evaluation, FDA conducts a microbial safety assessment. These assessments started in 2003 and evaluate the potential risk of the use of an antimicrobial drug used in food animals to contribute to antibacterial resistance in pathogens of human concern. The FDA has concluded that ceftiofur is safe for use in food-producing animals when used according to label directions and has confirmed this safety through multiple approvals since 2003.

The government monitors animal processing facilities, meat sold at retail and foodborne diseases in search of resistant organisms. While antibiotic-resistant organisms in foodborne pathogens occur, cephalosporin-resistant *Salmonella* infections in people remain low and have been decreasing, according to government data.[3]

DESPITE BEING INTRODUCED MORE THAN 25 YEARS AGO TARGET PATHOGENS REMAIN NEARLY 100% SUSCEPTIBLE TO CEFTIOFUR.[4,5]

CEFTIOFUR: STILL STRONG AFTER DECADES OF USE

Today, after more than 25 years of ceftiofur use in food-producing animals, our nationwide ongoing antimicrobial surveillance program shows that target pathogens continue to be nearly 100% susceptible to ceftiofur.[4,5] Zoetis sponsors the largest North American antibiotic resistance monitoring program in the animal health industry to help ensure ceftiofur is used carefully and remains effective. Our program began in 1999 and now includes participation of 35 diagnostic laboratories to monitor mastitis pathogens and respiratory disease resistance in cattle, swine and horses. Zoetis also cosponsors surveillance programs in the European Union with other animal health companies.

ZOETIS HAS INVESTED 26 YEARS OF ONGOING EDUCATION AND TRAINING TO SUPPORT PROPER USE OF CEFTIOFUR IN FOOD ANIMALS.

Responsible use of ceftiofur on the farm will help preserve its effectiveness against target pathogens and protect food safety. The Zoetis Field Force and Technical Services Teams have invested 26 years in ongoing education and training so veterinarians and farmers use ceftiofur products appropriately and within the label guidelines outlined by the FDA. The teams includes veterinarians, veterinary technicians, nutritionists, meat/food scientists and animal husbandry specialists with extensive practice, research and species-specific (cattle, swine, poultry, sheep, dogs, cats and horses) expertise. The teams advocate for, advise and train veterinary and livestock farmer customers on sound practices on the farm, such as proper nutrition, vaccination and veterinary oversight that reduces the need for disease treatment.

For more information about ceftiofur antibiotic products, visit our FAQ section on AvoidResidues.com.

ADDITIONAL RESOURCES

AvoidResidues.com
ZoetisPork.com/AvoidResidues
AHI.org
CDC.gov/NARMS
FoodDialogues.com
FoodInsight.org

[1] Ceftiofur is sold under Zoetis brand names and also sold as a generic by other companies.

[1] Food and Drug Administration. 2012 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals. Available at: http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM416983.pdf. Published September 2014. Accessed November 14, 2014.

[2] U. S. Department of Agriculture Food Safety and Inspection Service. United States National Residue Program for Meat, Poultry, and Egg Products. Available at: http://www.fsis.usda.gov/wps/wcm/connect/f511ad0e-d148-4bec-95c7-22774e731f7c/2011_Red_Book.pdf?MOD=AJPERES. Published May 2013. Accessed November 14, 2014.

[3] U.S. Food and Drug Administration. National Antimicrobial Resistance Monitoring System 2011 Executive Report. Available at: http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm407957.htm. Published 2013. Accessed November 5, 2014.

[4] Lindeman CJ, Portis E, Johansen L, Mullins LM, Stoltman GA. Susceptibility to antimicrobial agents among bovine mastitis pathogens isolated from North American dairy cattle, 2002-2010. *J Vet Diagn Invest* 2013;25(5):581-591.

[5] Portis E, Lindeman C, Johansen L, Stoltman G. A ten-year (2000-2009) study of antimicrobial susceptibility of bacteria that cause bovine respiratory disease complex — Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni — in the United States and Canada. *J Vet Diagn Invest* 2012;24(5):932-944.

***Residue Free Guarantee:** If you use a Zoetis-branded ceftiofur product according to label indications, and experience a violative ceftiofur milk or meat residue, Zoetis will compensate you for the beef market value of the animal or purchase the tanker of milk at fair market value. You must purchase the product from a Zoetis-approved supplier, use the product according to label indications, have documentation of the product purchase and treatment records, and have conducted training on appropriate use to ensure proper dose and route of administration of the product. Extra-label use as prescribed by a veterinarian is excluded from the guarantee. If you experience a ceftiofur residue violation after following label indications and the above steps, contact Zoetis Veterinary Medical Information and Product Support (VMIPS) at 800-366-5288 to report the situation.

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