

Cautions about using gentamicin, neomycin

Aminoglycosides compose a class of antibiotics that includes gentamicin and neomycin. When injected, these drugs tend to accumulate in the kidney, where they cause damage. It takes many months until they are cleared from the body, allowing treated animals to enter the human food chain.

Extra-label use

Two aminoglycosides approved for use in cattle are gentamicin and neomycin. The only approved use for gentamicin in beef cattle is as a topical pinkeye product. Neomycin is approved for use as a product given by mouth but not by injection.

The National Cattlemen's Beef Association (NCBA), the American Association of Bovine Practitioners (AABP; the largest organization of cattle veterinarians in the U.S.), the American Veterinary Medical Association (AVMA) and the Academy of Veterinary Consultants (AVC) have all passed resolutions indicating that aminoglycoside antibiotics should not be used in cattle, except as specifically approved by the Food and Drug Administration (FDA).

Although it's not expressly illegal to use gentamicin and neomycin in an "extra-label" fashion (i.e., injection for the treatment of pneumonia) under the direction of a veterinarian who has a valid veterinary client-patient relationship with you, the liability for any tissue residues falls to the producer and veterinarian. Because it is known that residues of these products can occur in kidney tissue for a very long period of time, and because of food safety concerns

raised by the use of these drugs in an extralabel fashion, veterinarians are discouraged from prescribing the use of injectable aminoglycosides.

No withdrawal period has been scientifically established in cattle for those veterinarians searching for directions in an extra-label-use scenario. The Food Animal Residue Avoidance Databank (FARAD) has established a harvest withdrawal of 18 months for gentamicin used in an extra-label manner (anything other than the recently approved pinkeye product). Because many cattle are harvested before they reach 18 months of age, this prolonged withdrawal time makes it unwise to inject gentamicin or neomycin in cattle of any age.

Including your vet

Because wise use of antibiotics is critically important to beef producers to ensure the safety and wholesomeness of the animals and meat products they sell, producers and their veterinarians should use products according to label directions whenever possible. Using products in any way that is not clearly approved on the label constitutes extra-label use. Extra-label use can include using a different dose than indicated on the label,

administering the product by a different route than indicated (i.e., injection rather than by mouth), or at a different frequency (i.e., every day rather than every three days).

Only licensed veterinarians have the privilege of prescribing drugs in extra-label fashion, and then with limitations. Some products are prohibited from any use in food animals, others cannot be used in an extra-label fashion, and use of any allowed product in a legal extra-label fashion must meet the requirements of the Animal Medicinal Drug Use Clarification Act (AMDUCA).

For a veterinarian to prescribe a legal extra-label use of an antibiotic for you to use, he or she must first establish a valid veterinary client-patient relationship. Then, your veterinarian must determine that there is no labeled drug for the use in question that is effective as labeled. The veterinarian is then required to first consider changing the regimen of the labeled compound, then consider the extra-label use of another drug currently approved for food animals.

Antibiotic considerations

Cost is not a valid consideration for extralabel use. In other words, if a product is labeled and effective for a disease condition, you cannot use an extra-label product just because it is less expensive. Even if a situation merits consideration of an extra-label use of an antibiotic, your veterinarian must consider whether there is adequate scientific information available to determine an appropriate withdrawal time. If not, the product cannot be used. At any point in this process, extra-label use of a product can be decided against.

Because we are fortunate to have a number of antibiotic choices that have been shown to effectively treat respiratory diseases, and there is no published clinical trial data to support the use of gentamicin to treat bovine respiratory disease (BRD), it is difficult to imagine a situation where extra-label use of gentamicin or neomycin can be justified and successfully defended if challenged.

Antibiotics are great tools for producing healthy animals and alleviating animal suffering, but they must be used responsibly to protect the wholesomeness and reputation of beef. The prudent use of antibiotics is the responsibility of all cattle producers and their veterinarians.

Information about AMDUCA, including a link to the regulations, may be viewed at www.fda.gov/cvm/amducatoc.htm.

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