



Use of Toltrazuril (and its metabolites) in Small Ruminants in the US

AMERICAN CONSORTIUM FOR SMALL RUMINANT PARASITE CONTROL

What is toltrazuril? It is an anti-protozoal drug. It is an anticoccidial agent.

Who regulates drug approval in the USA?

The Food and Drug Administration (FDA) regulates all drugs in the US. Medications must go through an approval process to be licensed for manufacture and use. Federal law prohibits the use, importation, and sale of drugs that the FDA and Environmental Protection Agency (EPA) have not approved.

Compounded forms of ponazuril, diclazuril, and toltrazuril are available to the public. What do we need to know?

Ponazuril

This is an FDA-approved product for horses only, to treat equine protozoal myeloencephalitis. The use of compounded ponazuril originating from bulk “active pharmaceutical ingredients” (API) in food animals is illegal under any circumstances in the US.

Diclazuril

This product is utilized in two forms, an equine oral pellet for the treatment of equine protozoal myeloencephalitis and a medicated feed for broiler chickens and growing turkeys to prevent coccidiosis. The extra-label use of this product is not permitted in both forms and is illegal. Therefore, the use of compounded diclazuril originating from bulk API in food animals is illegal under any circumstances.

Toltrazuril

There is no FDA-approved product in the US. Therefore, toltrazuril is illegal to use in food animals in the US in any form.



Why are these products available on the market if they are illegal?

These drugs may be approved for food animal use in other countries. However, drugs approved in other jurisdictions may not be legally imported and used in food animals in the United States, regardless of their label in other countries.

What classifies as a food animal?

In the US, a food animal is any animal species that is raised and used for food production or consumption by humans. This encompasses cattle, (dairy and beef), sheep, goats, swine, poultry (including egg-producing poultry), fish used for food, and honey bees. All sheep and goats are classified as food animals by FDA regardless of the purpose of ownership.

What is extra-label drug use (ELDU)?

ELDU describes the use of an approved drug in a manner that deviates in any way from the drug’s approved labeling, yet meets the conditions set forth by the Animal Medicinal Drug Use Clarification Act of 1994



AMDUCA) and US Food and Drug Administration (FDA) regulations. Using a drug in any way that is different from what is specified by the manufacturer on the FDA-approved drug label is called ELDU.

Veterinarians are legally the only individuals allowed to prescribe and use drugs in an extra-label manner in the US. When drugs are administered in an extra label manner, this alters the meat and milk withholding recommendations in food animals. Serious ramifications may occur if you use these products illegally.

Some sources may have compounds labeled and approved for use in other animals in other countries, but most toltrazuril is purchased online and is compounded by unknown sources without oversight and is untraceable. A great danger of using illegal, unregulated, compounded drugs is that its effectiveness nor safety is guaranteed. Producers have lost animals as a result with no recourse available. Legal repercussions can also ensue for the producer should residues of this product be found in meat/milk products that are intended to enter the food chain.

What other products are available to treat coccidiosis in small ruminants?

Products available to treat coccidiosis in small ruminants in the US are not FDA approved for use in sheep and goats. Extra-label drug use by a licensed veterinarian is required! Amprolium (Corid®) can be used as both a treatment and preventative for coccidiosis. It is important to remember that thiamine deficiency

If your sheep and/or goats need coccidia treatment (in the US), you cannot legally use toltrazuril (or its derivatives).

has been reported to occur secondary to administration of Corid®. Please consult your veterinarian prior to using Corid®. Sulfa medications can also be used to treat coccidiosis. Sulfa products require a prescription, so please consult your veterinarian.

What about coccidiostats?

There are several feed additives that can be used to prevent coccidiosis in sheep and goats. Bovatec® (lasalocid) is FDA-approved for confined sheep. Rumensin® (monensin) is FDA-approved for confined goats. Deccox® (decoquinate) is FDA-approved for young, non-lactating sheep and goats. Rumensin® can be toxic to dogs and equines (horses and related animals). Always use a feed mill to mix any feed containing a coccidiostat. If not mixed properly, toxicity can also occur. Coccidiostats do not kill the coccidial organism. Rather they slow down the shedding of coccidia in the environment. Therefore, they need to be fed well in advance of the risk period, approximately 21 days prior in order for them to be effective. Conventional dewormers will not treat or prevent coccidiosis.



This article originally appeared in the Small Ruminant Update (Spring 2024), newsletter by the University of Florida Small Ruminant Program. It was written by Brittany Diehl, DVM, MS. Clinical Assistant Professor and Small Ruminant Extension Specialist, University of Florida College of Veterinary Medicine, Gainesville, Florida.

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