Compounding Trilostane: Variations & Considerations

Trilostane, used to treat canine hyperadrenocorticism, was licensed for US use in 2008, but the FDA allowed for reformulation of licensed product if specific patients require the drug in unavailable strengths. The FDA does not allow compounding of trilostane from bulk ingredients. Before licensing, compounded trilostane was marketed by compounding pharmacies. In this study, the pharmaceutical properties of commercially compounded trilostane were compared with reformulation of the licensed product. Capsules (15, 45, 100 mg) were ordered from 8 internet pharmacies and compared with controls containing either inert material or 15-mg licensed product and proprietary capsules (30, 60 mg). In total, 96 batches of compounded capsules and 16 control batches were assayed for content and dissolution characteristics. Inert capsules did not contain any active ingredient. All 15-mg compounded controls using licensed product and the 30- and 60-mg proprietary controls met the acceptance criteria for content. The percentage label claim for commercially compounded products varied from 39% to 152.6% (mean, 97.7%); 36/96 (38%) of batches were below the acceptable criteria for content. All controls exceeded the criteria for dissolution, but 19/96 (20%) of compounded products were significantly lower. Nonproprietary compounded capsules may vary in strength and dissolution, potentially adversely affecting patient care.

Commentary

Use of approved drugs is encouraged over off-label use. Compounding FDA-approved veterinary products, however, is common for treating smaller dogs and cats so that certain dose ranges and tapers can be met. This study showed that not all compounding of trilostane by pharmacies produced equal results, even when multiple compounders are evaluated. In fact, the variation within some batches of trilostane is similar in some ways to the substantial variation noted in unregulated human nutraceuticals (eg, glucosamine chondroitin). Extensively varying doses can cloud the already complicated interpretation of diagnostics for canine hyperadrenocorticism and treatment choices. The bottom line is not necessarily that veterinarians should not order from compounding pharmacies, but that it pays to research and choose wisely which to use based on staff expertise.—Ewan Wolff, DVM

Source


See Update on the Use of Trilostane by Dr. Ellen Behrend at cliniciansbrief.com/trilostane-update-2011