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Animal & Veterinary

SucroMate Equine (deslorelin acetate) - Veterinarians

Dear Equine Veterinarian:

The U.S. Food and Drug Administration (FDA) recently approved SucroMate Equine (deslorelin acetate) for inducing ovulation within 48 hours of treatment in cyclic estrous mares with an ovarian follicle between 30 and 40 mm in diameter. Mares are treated once per estrus cycle with an intramuscular injection in the neck, given 48 hours before desired ovulation. Please see the approval notice in the Federal Register at <http://edocket.access.gpo.gov/2010/pdf/2010-32554.pdf>¹.

SucroMate Equine, manufactured by Thorn BioScience LLC, is available in the United States as an injectable, sustained-release suspension. The suspension comes in a 10 mL vial that can be used for 10 doses. The strength is 1.8 mg deslorelin acetate (1.7 mg deslorelin) per mL. SucroMate Equine is the only marketed FDA-approved animal drug that contains deslorelin as the active ingredient. Now that SucroMate Equine is approved and available for veterinary use in the United States, deslorelin should not be imported from other countries or compounded from bulk.

FDA rigorously evaluates an animal drug before approving it. As part of the evaluation process, the drug company must prove to FDA that the drug is safe and effective for a specific use in a specific animal species. The drug company must also prove that the drug's manufacturing process is adequate to preserve the drug's identity, strength, quality, and purity. After FDA approves the animal drug, the agency continues to monitor the drug's safety and effectiveness. FDA also continues to monitor the drug's manufacturing process to make sure quality and consistency are maintained from batch to batch. An animal drug that is compounded from bulk drug ingredients is not FDA-approved. This means FDA has not evaluated the safety and effectiveness of the compounded drug or the adequacy of the manufacturing process.

In prescribing FDA-approved SucroMate Equine to induce ovulation, you are providing your clients and their mares with the only marketed deslorelin product shown to be safe and effective in horses. Also, SucroMate Equine is the only marketed deslorelin product that is manufactured to meet FDA's strict standards for quality, purity, and potency.

You may have specific patients that require deslorelin in strengths or forms that are not offered by SucroMate Equine. In these limited cases, deslorelin can only be legally compounded by using FDA-approved SucroMate Equine as the starting material. Additional requirements and information on legal animal drug compounding are available in Title 21, Code of Federal Regulations, Section 530.13².

At FDA's Center for Veterinary Medicine (CVM), we are committed to promoting and protecting animal health by ensuring safe and effective drugs are available for animals.

For more information, please contact the CVM Communications Staff at 240-276-9300 or AskCVM@fda.hhs.gov.

Sincerely,

FDA's Center for Veterinary Medicine

Links on this page:

1. <http://edocket.access.gpo.gov/2010/pdf/2010-32554.pdf>
2. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=530&showFR=1>