FDA Approved Drugs vs. Compounded Products and Veterinary Medical Devices

Equine veterinarians are increasingly challenged to provide sound medical care while operating within economic restrictions. In efforts to maintain client goodwill and minimize treatment costs, veterinarians may consider non-Food and Drug Administration (FDA) approved product alternatives, such as compounded drugs and veterinary medical devices. When veterinarians choose to administer products that have not undergone equivalent clinical testing for safety and efficacy in the horse, unforeseen risks may arise. Therefore, it is important for veterinarians to understand and, if appropriate, communicate the importance of using FDA approved drugs, such as Adequan® i.m. (polysulfated glycosaminoglycan) and BetaVet® (betamethasone sodium phosphate & betamethasone acetate injectable suspension).

Adequan® i.m.

INDICATIONS
For the intramuscular treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.

IMPORTANT SAFETY INFORMATION

There are no known contraindications to the use of intramuscular Adequan® i.m. brand Polysulfated Glycosaminoglycan in horses. Studies have not been conducted to establish safety in breeding horses. WARNING: Do not use in horses intended for human consumption. Not for use in humans. Keep this and all medications out of the reach of children. CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Adequan® i.m. and BetaVet® are FDA Approved Pioneer Drugs.

There is NO generic Adequan® i.m. (polysulfated glycosaminoglycan) or BetaVet® (betamethasone sodium phosphate & betamethasone acetate injectable suspension).

What About Compounded Veterinary Drugs?

Are Veterinary Medical Devices Equivalent to FDA Approved Drugs?

### FDA Pioneer Drugs:
- A drug that has undergone the safety of limited clinical studies to demonstrate safety and efficacy in accordance with Good Laboratory Procedures (GLP).
- A general drug is bioequivalent to a pioneer drug in dosage form, efficacy, safety and strength; route of administration, quality, and intended use.
- The product is manufactured under FDA mandated Good Manufacturing Practices (GMPs) in regularly inspected plants.
- Therapeutic consistency, product quality, accurate shelf life, and scientifically substantiated labeling are FDA mandated.
- Stringent standards for drug purity and efficacy must be established and stability data generated to determine expiration dating.
- Detailed records of each batch of drug produced are maintained and retained for future testing.
- The manufacture conducts ongoing surveillance for adverse events involving lack of safety and efficacy and must regularly provide reporting data to the FDA.

### Generic Drugs:
- Any drug manipulated to produce a dosage form (other than that provided in the protocol) for use in labeling of the approved drug product.
- Compounded drugs are not considered generic drugs.
- Neither cost nor convenience is justification for using compounded preparations. Compounding provides a customized formulation for the special needs of a particular patient, whose importance is established in written protocols or information provided by a veterinarian-client relationship (VCPR).
- Stringent labeling standards for off-label use must be established and stability data generated to determine expiration dating.
- Use of a human drug in an animal constitutes off-label use.

### Comounded Drugs:
- A 2016 study evaluated the efficacy of IV administration of a combination product containing hyaluronan, sodium chondroitin sulfate, with or without glucocorticoids for prevention or treatment of osteoarthritis in 32 healthy 2- to 5-year-old horses.
- The study concluded that caution should be used when administering the product to foals, particularly when administering glucocorticoids; as it may cause delayed bone closure, resulting in improper bone formation.
- Veterinary device labeling and ingredients may appear very similar to FDA approved drugs.
- For example, some products contain only monosulfated chondroitin sulfate, which is not chemically equivalent to polysulfated glycosaminoglycan (PSGAG) in Adequan®. Adequan® contains 3-4 sulfate esters per disaccharide molecule, differs in structure and function, and no bioequivalent product exists.

### Veterinary Medical Devices:
- Any drug manipulated to produce a dosage form other than that approved for its human use is considered a medical device.
- The labeling of medical devices used within veterinary medicine may not contain language describing the product as a device if the practitioner’s questions regarding the status of a product, as he should contact the manufacturer.

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In summary, the significance of FDA approval is essential for both veterinarians and clients to understand. For a new drug to satisfy each stage of the FDA approval process, often takes years, and practitioners should consider the benefits of using approved drugs over non-approved alternatives. Stringent FDA approval requirements provide the benchmark for veterinary drug safety and efficacy, and allow practitioners to provide optimal care to their patients.

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**The Difference is in the Details**
**BetaVet® (betamethasone sodium phosphate and betamethasone acetate injectable suspension)**

**For Intra-articular (I.A.) use in Horses.**

**INDICATION:** BetaVet® (betamethasone sodium phosphate and betamethasone acetate injectable suspension) is indicated for the control of pain and inflammation associated with osteoarthritis in horses.

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS:** BetaVet® is contraindicated in horses with hypersensitivity to betamethasone. Intra-articular injection of corticosteroids for local effect is contraindicated in the presence of septic arthritis.

**WARNINGS:** Do not use in horses intended for human consumption. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Additionally, corticosteroids administered to dogs, rabbits and rodents during pregnancy have resulted in congenital anomalies. Before use of corticosteroids in pregnant animals, the possible benefits should be weighed against potential hazards. **Human Warnings:** Not for use in humans. Keep this and all medications out of the reach of children.

**PRECAUTIONS:** Corticosteroids, including BetaVet®, administered intra-articularly are systemically absorbed. Do not use in horses with acute infections. Acute moderate to severe exacerbation of pain, further loss of joint motion, fever, or malaise within several days following intra-articular injection may indicate a septic process. Because of the anti-inflammatory action of corticosteroids, signs of infection in the treated joint may be masked. Due to the potential for exacerbation of clinical signs of laminitis, glucocorticoids should be used with caution in horses with a history of laminitis, or horses otherwise at a higher risk for laminitis. Use with caution in horses with chronic nephritis, equine pituitary pars intermedia dysfunction (PPID), and congestive heart failure. Concurrent use of other anti-inflammatory drugs should be approached with caution. Consider appropriate wash out times prior to administering additional NSAIDs or corticosteroids.

**ADVERSE REACTIONS:** Adverse reactions reported during a field study of 239 horses of various breeds which had been administered either BetaVet® [n=119] or a saline control [n=120] at five percent [5%] and above were: acute joint effusion and/or local injection site swelling (within 2 days of injection), 15% BetaVet® and 13% saline control; increased lameness (within the first 5 days), 6.7% BetaVet® and 8.3% saline control; loose stool, 5.9% BetaVet® and 8.3% saline control; increased heat in joint, 2.5% BetaVet® and 5% saline control; and depression, 5.9% BetaVet® and 1.6% saline control.

**SHAKE WELL IMMEDIATELY BEFORE USE.** For additional safety information, please see full prescribing information.

**CAUTION:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.
To report an adverse event for any American Regent Animal Health product:

- **Contact American Regent Animal Health**
  - Toll-free: (800) 734-9236
  - Email: pv@americanregent.com

- **Contact the Center for Veterinary Medicine**
  - Call: (888) FDA-VETS
  - Email: AskCVM@fda.hhs.gov

References: