BetaVet® (betamethasone sodium phosphate and betamethasone acetate injectable suspension) is indicated for the control of pain and inflammation associated with osteoarthritis in horses.
The only dual-action betamethasone product proven safe and effective in horses.

- BetaVet® is a sterile aqueous suspension of betamethasone acetate in betamethasone sodium phosphate injection.
- Intra-articular (IA) corticosteroid injections, when used appropriately, are considered a cornerstone of therapy to reduce inflammation.
- Target animal safety (TAS) study® supported the FDA approval of BetaVet® when administered IA to horses in a maximum of 2 joints at a one-time dosing of 9 mg per joint.


Betavet® (betamethasone sodium phosphate and betamethasone acetate injectable suspension)

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. Please see accompanying Full Prescribing Information or at betavetequine.com. For additional Important Safety Information, please see next page.
A unique formula backed by science.

- **Controls pain and inflammation** associated with equine osteoarthritis
- **Unique equine formula with 2 active ingredients:**
  - Betamethasone sodium phosphate (3.15 mg²), a highly soluble betamethasone ester with a rapid onset of action¹
  - Betamethasone acetate (2.85 mg²), a less soluble betamethasone ester with prolonged action
- **Time to peak plasma (Tmax) concentrations** achieved in as little as 4.5 to 8 hours*  
  *Clinical significance of these results is unknown.

Pivotal field studies show over 75% efficacy.²

- **BetaVet® clinical success rate of 75.73%** (n=87) compared to Saline (Control) clinical success rate of 52.52% (n=61)
- **Field efficacy study** based on a negative control, randomized masked trial of 239 horses — BetaVet® n=114; Saline (Control) n=115
- **Clinical success defined** as improvement in one lameness grade according to the AAEP lameness scoring system, Day 5 after treatment

**What sets BetaVet® apart?**

<table>
<thead>
<tr>
<th>FDA-approved product benefits</th>
<th>BetaVet®</th>
<th>Other IA corticosteroids</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONLY dual-action equine corticosteroid with two active ingredients²</td>
<td>✔️</td>
<td>✗</td>
</tr>
<tr>
<td>Fastest time to maximum measured plasma concentration post-IA injection²</td>
<td>✔️</td>
<td>✗</td>
</tr>
<tr>
<td>No deleterious effects shown on equine articular cartilage⁶</td>
<td>✔️</td>
<td>✗</td>
</tr>
<tr>
<td>Wider therapeutic index for betamethasone anecdotally reported for laminitis risk⁵</td>
<td>✔️</td>
<td>✗</td>
</tr>
<tr>
<td>Meets ARCI, RMTC, USEF requirements for shortest withdrawal time (7 days)⁶, ⁷, ⁸</td>
<td>✔️</td>
<td>✔️</td>
</tr>
</tbody>
</table>

*See triamcinolone reference #8.

The most common adverse events included local swelling, mild increases in lameness, loose stool, increased heat in the treated joint, depression, anxiety and inappetence.

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

**Dosing and administration**

- **Shake well immediately before use.**
- **Using strict aseptic technique,** administer BetaVet® 1.5 mL (9 mg total betamethasone) per joint by intra-articular injection.
- **May be administered concurrently** in up to 2 joints per horse.
- **Use immediately** after opening; discard any remaining contents.

**CAUTION:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.
From the manufacturer of Adequan® i.m. (polysulfated glycosaminoglycan), trusted by veterinarians for more than 30 years.

Want to learn more or place an order?

- Contact your American Regent, Inc., Sales Representative
- Call 1-800-458-0163
- Visit betavetequine.com

5. Frisbie D. New Research and Regulatory Issue Associated with Corticosteroids. AAEP Proceedings; November 26-29, 2000; San Antonio, TX.
6. ARCI Controlled Therapeutic Medication Schedule for Horses; V4.0 (Rev. April 20, 2017)
7. RMTC Approved Controlled Therapeutic Medications. 2 Feb 2016.

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PP-BV-US-0045 (v2.0)

Please see accompanying Full Prescribing Information or at betavetequine.com.
Betamethasone sodium phosphate and betamethasone acetate injectable suspension

**DESCRIPTION**

Betamethasone sodium phosphate and betamethasone acetate are designated as 9-fluoro-11β,17α,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 21-(disodium phosphate). 11β-17α,21-Trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 21-acetate.

Chemically, it is 9-Fluoro-11β,17α,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 21-acetate.

**PRECAUTIONS**

Corticosteroids, including BETAVET, administered intra-articularly are systematically 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. Appropriate examination of joint fluid is necessary to exclude a septic process. If bacterial infection is present, appropriate antibacterial therapy should be instituted immediately. Additional doses of corticosteroids should not be administered until joint sepsis has been definitively ruled out.

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 laminitis or a higher risk for laminitis.

Use with caution in horses with chronic, nephritis, equine polyarthritis/aortic dysplasia (PAD), and congestive heart failure.

Concurrent use of other anti-inflammatory drugs, such as NSAIDs or other corticosteroids, should be approached with caution. Due to the potential for systemic exposure, concurrent use of NSAIDs or other corticosteroids may increase the risk of gastrointestinal, renal, and other toxicity. 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) are summarized in Table 1. In a study with 8 horses in each group, intra-articular injection of BETAVET was compared with oral administration of the betamethasone acetate concentration was below the limit of quantification in plasma.

**CLINICAL PHARMACOLOGY**

Betamethasone is a potent glucocorticoid steroid with anti-inflammatory and immunosuppressive properties. Depending upon their physico-chemical properties, drugs administered intra-articularly may enter the general circulation because the synovial joint cavity is in direct equilibrium with the surrounding blood space. After the intra-articular administration of 5 mg BETAVET in horses, there were quantifiable concentrations of betamethasone (above 1.0 ng/mL) in the plasma. Maximal plasma concentrations (Cmax) and time to Cmax (Tmax) values ranged from 2.70 to 3.48 ng/mL, and 4.5 to 9.0 hours, respectively. The effective plasma terminal elimination half-life ranged from 4 to 8 hours. The non-compartmental area under the curve to the limit of quantification (AUC0-t) ranged from 29.24 to 42.36 ng·h/mL. In contrast, the betamethasone disodium phosphate concentrations and all of the betamethasone acetate concentrations were below the limit of quantification in plasma.

**EFFECTIVENESS**

A negative control, randomized, masked field study provided data to evaluate the effectiveness of BETAVET administered at 1.5 mL (0.9 mg betamethasone acetate) for the control of pain and inflammation associated with arthritic conditions in horses. A total of 219 horses received BETAVET and 120 horses received saline. 229 horses were included in the final effectiveness analysis. Clinical success was defined as improvement in one lameness grade according to the AHP lameness grading system on Day 5 following treatment. Table 2 summarizes the clinical success and failure in each treatment group on Day 5. The success rate for horses in the BETAVET group was statistically significant (68.08%) compared to the control (35.71%)

**STORAGE CONDITIONS**

Store at 25°C (77°F) or below. Store in a dry place.

**HOW SUPPLIED**

BETAVET, containing 30 mg betamethasone acetate (6 mg betamethasone sodium phosphate) in 5 mL vials.

NDC 10797-720-01 5 mL Vials  Package of boxes of 1

**SHAKE WELL BEFORE USING**

Approved by FDA under IND # 141-458

AMERICAN RECENT, INC. ANIMAL HEALTH

Shirley, NY 11967

(1-888-354-4657)

Rev. 8/2021

ROH53A

**Table 1. Adverse Reactions**

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Number (%) of BETAVET treated horses</th>
<th>Number (%) of saline treated horses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute joint effusion and/or local injection site swelling (within 2 days of injection)</td>
<td>18 (15%)</td>
<td>16 (13%)</td>
</tr>
<tr>
<td>Premature laminitis (within the first 5 days)</td>
<td>8 (6.7%)</td>
<td>10 (8.3%)</td>
</tr>
<tr>
<td>Loose stool</td>
<td>7 (5.9%)</td>
<td>10 (8.3%)</td>
</tr>
<tr>
<td>Increased heat in joint</td>
<td>2 (1.7%)</td>
<td>2 (1.6%)</td>
</tr>
<tr>
<td>Depression</td>
<td>7 (5.9%)</td>
<td>2 (1.6%)</td>
</tr>
<tr>
<td>Agitation</td>
<td>6 (5.2%)</td>
<td>4 (3.3%)</td>
</tr>
<tr>
<td>Oilward swelling of treated joint (5 or more days after injection)</td>
<td>3 (2.5%)</td>
<td>4 (3.3%)</td>
</tr>
<tr>
<td>Hiccups</td>
<td>4 (3.4%)</td>
<td>3 (2.5%)</td>
</tr>
<tr>
<td>Dry cough</td>
<td>2 (1.7%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Excessive sweating</td>
<td>1 (0.8%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Acute-onset bearing lameness</td>
<td>1 (0.8%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Laminitis</td>
<td>1 (0.8%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

The incidence rate of injection site reactions (injection site swelling (in many horses on multiple days in all treatment groups) to excessive fluid with swelling, pain, and lameness; 4x group only) Injection site reactions were observed most commonly on treatment days, and generally decreased in number and severity over subsequent days. The incidence of injection site reactions increased significantly after the second and third injection (number of abnormalities noted on day 10 = day 5 + day 0). In the BETAVET treated groups the number and severity of the injection site reactions were dose dependent. The 4X BETAVET group had the greatest overall incidence and severity of injection site reactions, which included heat, swelling, pain, bleeding, and tricking the hocks up at rest. The control group and 4X group (which received initial injection volumes) had a similar incidence of injection site reactions; however, the severity of reactions was greater in the 4X group.

Absolute neutrophils were statistically significantly higher in the BETAVET treated groups as compared to the control group. Trends toward a decrease in lymphocytes and monocytes, and an increase in monocytes were identified in the BETAVET treated groups after the initial dose of BETAVET. Individual animal values for white blood cells generally remained within the reference range. BETAVET treated horses also had a trend toward increased blood glucose after the initial dose. Some individual animals showed mild increases in blood glucose above the reference range.