KEY POINTS
• Consistent manufacturing and quality control results in a tablet that has reliable strength and stability from batch to batch
• Data supported by the first and only efficacy and safety study involving PPID.¹
• Prascend is available only with a veterinary prescription
• Resources available for the veterinarian to help diagnose and manage PPID successfully

FACTS
• Common signs of PPID:
  - Decreased athletic performance
  - Change in attitude/lethargy
  - Delayed hair coat shedding (subtle)
    > Patches of longer and lighter hair in summer
    > Backs of legs, jugular groove, and shedding later than herd mates
  - Regional hypertrichosis/hirsutism
  - Change in body conformation
  - Regional adiposity
    > Fat on top of neck, tail head, above eyes
  - Laminitis

PRASCEND®
PERGOLIDE MESYLATE
AT-A-GLANCE
ONLY FDA approved product for the management of clinical signs of Pituitary Pars Intermedia Dysfunction (PPID) in horses

Horses as young as 7 years of age², have been diagnosed with PPID. Earlier diagnosis may offer horses suffering from the disease a better quality of life, so ID PPID early.

Studies have shown that the clinical signs of PPID are often under-recognized.³

PRASCEND FEATURES
Produced in GMP approved facilities unlike most compounding pharmacies

PRASCEND BENEFITS
Peace of mind knowing Prascend is consistently manufactured under quality-controlled conditions

24 month expiration date

Proven stable up to product expiration date based on documented stability data under recommended storage conditions

Packaged in 60 ct and 160 ct blister packs

Maintains the integrity of the product without degradation associated with many compounded products⁵,⁶

See the difference with Prascend

BEFORE

AFTER 6 MONTHS

Important safety information: PRASCEND® is for use in horses only. Treatment with PRASCEND® may cause loss of appetite. Most cases are mild. Weight loss, lack of energy, and behavioral changes also may be observed. If severe, a temporary dose reduction may be necessary. PRASCEND® has not been evaluated in breeding, pregnant, or lactating horses and may interfere with reproductive hormones in these horses. PRASCEND Tablets should not be crushed due to the potential for increased human exposure.

²Schott HC. Pars pituitary intermedia dysfunction: challenges of diagnosis and treatment. In: Proceedings from the 52nd American Association of Equine Practitioners Annual Convention; December 2–6, 2006; San Antonio, TX.
⁴See the differences with Prascend.
Prascend® (pergolide mesylate)

Tablets, 1 mg

Dopamine receptor agonist for oral use in horses only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Description: Prascend Tablets are rectangular light red colored, half-scored tablets containing 1 mg pergolide, as pergolide mesylate. Pergolide mesylate is a synthetic ergot derivative and is a potent dopamine receptor agonist. The chemical name of pergolide mesylate is 8F-[(Methylthio)methyl]-6-propylergoline 6-propylpropylmonomethanesulfonate. The chemical structure is:

\[
\text{Prascend} = \text{a dopamine agonist} \text{ since these agents may diminish the effectiveness of Prascend.}
\]

Adverse Reactions: A total of 122 horses treated with Prascend Tablets for 8 weeks were included in a field study safety analysis.

Table 2 Summary of the most common adverse reactions (N=122)

<table>
<thead>
<tr>
<th>Clinical sign</th>
<th># Cases</th>
<th>Cases (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreased appetite</td>
<td>40</td>
<td>32.8</td>
</tr>
<tr>
<td>Lameness</td>
<td>22</td>
<td>18.0</td>
</tr>
<tr>
<td>Diarhoea/Loose stool</td>
<td>12</td>
<td>9.8</td>
</tr>
<tr>
<td>Colic</td>
<td>12</td>
<td>9.8</td>
</tr>
<tr>
<td>Lethargy</td>
<td>12</td>
<td>9.8</td>
</tr>
<tr>
<td>Abnormal Weight Loss</td>
<td>11</td>
<td>9.0</td>
</tr>
<tr>
<td>Laminits*</td>
<td>10</td>
<td>8.2</td>
</tr>
<tr>
<td>Heart murrmur</td>
<td>10</td>
<td>8.2</td>
</tr>
<tr>
<td>Death</td>
<td>8</td>
<td>6.6</td>
</tr>
<tr>
<td>Tooth disorder</td>
<td>8</td>
<td>6.6</td>
</tr>
<tr>
<td>Skin abscess</td>
<td>7</td>
<td>5.7</td>
</tr>
<tr>
<td>Musculoskeletal pain</td>
<td>6</td>
<td>4.9</td>
</tr>
<tr>
<td>Behavior change</td>
<td>6</td>
<td>4.9</td>
</tr>
</tbody>
</table>

* Three new cases and 7 pre-existing, recurring cases of laminitis were noted.

** Enrolled horses were diagnosed with PPID based on the presence of hirsutism and an abnormal pre-study endocrine test result. All horses were treated with 2 mcg/kg Prascend (to the nearest one-half tablet) orally once daily for the first three months. If the endocrine test result on Day 90 was normal or adequately improved, the horse continued on the same dose through Day 180. If the endocrine test result on Day 90 was abnormal, the dose increased to 4 mcg/kg given once daily through Day 180. Forty-seven (41.7%) of the 113 horses included in the effectiveness database required a dose increase at Day 90. Improvement was noted in scores for all clinical signs categories and in mean results for endocrine tests.

Table 4 Percent of Animals with Improvement in Clinical Signs Relative to Baseline Scores

<table>
<thead>
<tr>
<th>Test</th>
<th># Animals</th>
<th>Baseline</th>
<th>Day 90 (%)</th>
<th>Day 180 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTH (pg/mL)</td>
<td>20</td>
<td>73.53</td>
<td>51.12</td>
<td>45.08</td>
</tr>
<tr>
<td>DST* (mcg/dL)</td>
<td>93</td>
<td>3.12</td>
<td>1.39</td>
<td>1.47</td>
</tr>
</tbody>
</table>

* Dexamethasone suppression test: Post dexamethasone suppression test (%)

Animal Safety: In a six month target animal safety study healthy adult horses received Prascend administered orally, once daily, at doses of either 0 mcg/kg, 4 mcg/kg, 6 mcg/kg, or 8 mcg/kg (6X, 1X, 1.5X, or 2X the maximum recommended dose). There were eight healthy horses (four males and four females) in each treatment group. Doses were prepared by dissolving tablets in approximately 10 mL of a 50% sugar water solution. Prascend treated groups had lower mean heart rates and higher mean temperatures than the control group. Horses in all treatment groups had minimum heart rates within the normal range and maximum temperatures below 101.5°F. One 1.5X horse experienced a mild episode of spasmodic colic on Day 3 that resolved after treatment with fenugreek meglumine. Mean red blood cell counts and hemoglobin values were lower in Prascend treated groups as compared to the control group. Other hematology parameters including hemocrit, white blood cells, absolute neutrophils, and absolute lymphocytes exhibited mild, transient decreases as compared to the control group. The hematocrit parameters generally decreased over the first 30 days after treatment initiation and then returned to values similar to pre-treatment levels. No treatment related alterations were identified on histopathology evaluation of bone marrow.

Storage: Store at or below 25°C (77°F).

How Supplied: Prascend (pergolide mesylate) Tablets are available in 1 mg strength - packaged 10 tablets per blister and 60 or 160 tablets per carton.

NDC 0010-4489-01 - 60 tablets
NDC 0010-4489-02 - 160 tablets

References:
2. Boehringer Ingelheim Vetmedica, Inc. St. Joseph, MO 64056 U.S.A. Made in Japan and packaged in Germany. Prascend® is a registered trademark of Boehringer Ingelheim Vetmedica GmbH under license to Boehringer Ingelheim Vetmedica, Inc. © 2011 Boehringer Ingelheim Vetmedica, Inc. All Rights Reserved.