

# Zygoldide<sup>®</sup>

(pergolide tablets)



The **first FDA approved** generic peppermint-flavored pergolide tablet for the treatment of Pituitary Pars Intermedia Dysfunction (PPID).



**Peppermint flavor**  
to support consistent  
daily use



**360-degree, half-scored**  
tablets for flexible,  
accurate dosing



**Cost-effective**  
treatment<sup>1</sup>

# What is PPID?

(Equine Cushing's Disease)

Pituitary Pars Intermedia Dysfunction (PPID), also known as Equine Cushing's Disease, is an age-related hormonal disorder, caused by changes in the pituitary gland. The condition results from a decline in dopamine-producing neurons in the brain. While most common in older horses, developing in over 20% of horses aged 15 and older, it can also occur in younger horses. If left untreated, the pituitary gland overproduces hormones that lead to widespread endocrine dysfunction.<sup>(2)</sup>

## Common Symptoms

No one wants to watch their horse struggle. Be on the lookout for common symptoms that can help with early detection of PPID so you can help your horse stay healthy.

- **Coat changes:** Long, shaggy or abnormal shedding hair coat.
- **Physical changes:** Muscle loss, low energy and potential weight loss
- **Abnormal sweating:** Excessive or decreased sweating
- **Laminitis:** Increased risk of hyperinsulinemia-associated laminitis.
- **Chronic infections:** More susceptible to infections including sinus and hoof abscesses
- **Increased thirst:** Leads to increased drinking and urination

Clinical signs of PPID can vary and affected horses may show one or several symptoms.

(1) Market data on file

(2) Schott HC 2nd, Strachota JR, Marteniuk JV, Refsal KR. Long-term response of equids with pituitary pars intermedia dysfunction to treatment with pergolide. *J Vet Intern Med.* 2025;39:e70109. <https://doi.org/10.1111/jvim.70109>

## Treatment Options



While there is no cure, this disease can be managed through veterinary care and medication like Zygolide® (pergolide tablets).

- **Medication:** The only FDA-approved treatment is pergolide tablets to help lower hormone levels and improve symptoms. Zygolide® is the first to market generic peppermint flavored pergolide tablets.
- **Wellness Care:** Ensure careful management of body condition, hair coat, hooves, teeth, and parasite control. PPID horses should always have access to plenty of water if thirst increases.
- **Nutrition:** Carefully manage weight and body condition in horses with PPID, with feed choices tailored to body condition and insulin regulation status.
- **Monitoring:** Regular monitoring of your horse's body condition, weight, soundness and endocrine bloodwork is recommended. Work with your veterinarian to adjust diet or medication as needed.



(image not scaled to size)

# What is Zygolide® (pergolide tablets)?

Zygolide® is the first-to-market generic, peppermint-flavored pergolide tablet. Each tablet contains 1 mg of pergolide and is bioequivalent to the pioneer product when administered orally to horses.

FDA approval of generics requires rigorous testing to confirm bioequivalence, which ensures the same safety, efficacy, and therapeutic effect as the pioneer product. You can expect Zygolide® to perform to the same clinical standard, even in challenging cases.

## Easy Dosing for your Unique Horse

Every horse is different, that's why Zygolide® tablets are half-scored on all sides, making it easy to split tablets for accurate dose adjustments. This provides easy dosing options to meet the unique needs of your horse.



**360-degree,  
half-scored tablet**  
*(image not scaled to size)*

Zygolide® tablets come in a peppermint flavor, designed and formulated to be appealing to horses, helping to ensure consistent daily dosing for effective management of PPID.

## Flavor Supports Compliance

PPID is a life-long disease, which makes consistent treatment critical. Zygolide's® peppermint flavor provides an advantage in managing compliance and has been well accepted in horses in palatability studies. In one study comparing peppermint, anise, apple, and orange flavors, peppermint was among the top preferred.<sup>(3)</sup>

These findings suggest that flavors like peppermint can enhance palatability in equine formulations, resulting in the potential for enhanced compliance.

## Helping Your Horse Overcome PPID Challenges

Watching your horse struggle with age-related challenges is never easy. When the strong horse who used to carry you confidently over hills starts to slow down, you want a treatment like Zygolide® (pergolide tablets) that helps them feel their best again.

*Zygolide® tablets should not be crushed due to potential for increased human exposure. Pregnant or lactating women should wear gloves when administering this product.*

## Why Choose Zygolide®?

**FDA-approved, peppermint-flavored pergolide tablets that make managing PPID easier with:**



Peppermint flavor to support consistent daily use



360-degree, half-scored tablets for flexible dosing



Cost-effective treatment<sup>(1)</sup>

**Help your horse feel their best so you can enjoy more happy moments together.**

*(3) Francis JM, Neander CR, Roeder MJ, Perry EB. The influence of topically applied oil-based palatants on eating behavior in horses. J Equine Vet Sci. 2020;91:102995. <https://doi.org/10.1016/j.jevs.2020.102995>*

# Zygotide®

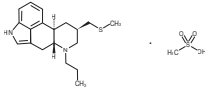
(pergolide tablets)

## 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:** Zygotide® tablets are elliptical white 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 6β-[(Methylthio) methyl]-6-propylpergolone monomethanesulfonate. The chemical structure is:



**Indication:** For the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (Equine Cushing's Disease) in horses.

**Dosage and Administration:** Administer orally at a starting dose of 2 mcg/kg once daily. Dosage may be adjusted to effect, not to exceed 4 mcg/kg daily.

It has been reported that pergolide tablets may cause eye irritation, an irritating smell, or headache when Zygotide tablets are split or crushed. Zygotide tablets should not be crushed due to the potential for increased human exposure and care should be taken to minimize exposure when splitting tablets. The tablets are scored and the calculated dosage should be provided to the nearest one-half tablet increment (see Table 1).

Table 1 Dosing Table		
Body weight	Dosage	
	2 mcg/kg	4 mcg/kg
136 - 340 kg (300 - 749 lb)	0.5 tablet	1 tablet
341 - 567 kg (750 - 1,249 lb)	1 tablet	2 tablets
568 - 795 kg (1,250 - 1,749 lb)	1.5 tablets	3 tablets
796 - 1,022 kg (1,750 - 2,249 lb)	2 tablets	4 tablets

Dosing should be titrated according to individual response to therapy to achieve the lowest effective dose. Dose titration is based on improvement in clinical signs associated with Pituitary Pars Intermedia Dysfunction (PPID) and/or improvement or normalization of endocrine tests (for example, dexamethasone suppression test or endogenous ACTH test).

In some cases, adverse events were reported after a dose increase (see **Post-Approval Experience**). If signs of dose intolerance develop, the dose should be decreased by half for 3 to 5 days and then titrated back up in 2 mcg/kg increments every 2 weeks until the desired effect is achieved.

**Contraindications:** Zygotide is contraindicated in horses with hypersensitivity to pergolide mesylate or other ergot derivatives.

**Warnings:** Do not use in horses intended for human consumption.

Keep Zygotide in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

Dogs have eaten pergolide tablets that were placed in food intended for horses or dropped during administration of the tablets to the horses. Adverse reactions may occur if animals other than horses ingest Zygotide tablets (see **Post-Approval Experience**).

**Human Warnings: Not for use in humans.** Do not ingest the product. Keep this and all medications out of the reach of children. Zygotide should not be administered by persons who have had adverse reactions to ergotamine or other ergot derivatives.

Pergolide, like other ergot derivatives, may cause emesis, dizziness, lethargy or low blood pressure.

**Pregnant or lactating women should wear gloves when administering this product.**

It has been reported that pergolide tablets may cause eye irritation, an irritating smell, or headache when pergolide tablets are split or crushed. Zygotide tablets should not be crushed due to the potential for increased human exposure and care should be taken to minimize exposure when splitting tablets. Store this product separately away from human medicinal products and handle this product with care to avoid accidental ingestion.

In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

**Precautions:** Treatment with Zygotide may cause inappetence.

The use of Zygotide in breeding, pregnant, or lactating horses has not been evaluated. The effects of pergolide mesylate on breeding, pregnant, or lactating horses has not been known; however, the pharmacologic action of pergolide mesylate may interfere with reproductive functions such as lactation. Pergolide tablets are approximately 90% associated with plasma proteins. Use caution if administering Zygotide with other drugs that affect protein binding. Dopamine antagonists, such as neuroleptics (phenothiazines, domperidone) or metoclopramide, ordinarily should not be administered concurrently with Zygotide (a dopamine agonist) since these agents may diminish the effectiveness of Zygotide.

**Adverse Reactions:**

**Pre-Approval Experience:** A total of 122 horses treated with pergolide tablets for six months were included in a field study safety analysis.

Table 2 Summary of the most common adverse reactions (N=122)		
Clinical sign	# Cases	Cases (%)
Decreased appetite	40	32.8
Lameness	22	18.0
Diarrhea/Loose stool	12	9.8
Colic	12	9.8
Lethargy	12	9.8
Abnormal Weight Loss	11	9.0
Laminitis*	10	8.2
Heart murmur	10	8.2
Death	8	6.6
Tooth disorder	8	6.6
Skin abscess	7	5.7
Musculoskeletal pain	6	4.9
Behavior change	6	4.9

\*Three new cases and 7 pre-existing, recurring cases of inappetence or decreased appetite occurred at one or more meals in 40 of 122 horses treated with pergolide tablets.

At the baseline evaluation 1.6% of owners reported a history of inappetence or decreased appetite as compared to the 32.8% of horses that experienced inappetence or decreased appetite during the study. Most cases of inappetence were transient and occurred during the first month of treatment; however, some horses experienced sporadic inappetence throughout the study. Two horses required a temporary reduction in dose due to inappetence during the first month of the study. Both horses returned to their original dose within 30 days.

Weight loss occurred in more than half of the horses in this study; however, weight loss that was considered abnormal was only reported in 11 horses.

Lethargy was reported in 9.8% of horses during the study, and was not reported in any horses at the baseline evaluation.

Behavioral changes were noted in 6 horses including aggression, kicking, agitation, nervous behavior and increased activity. One horse required a temporary reduction in dose due to energetic behavior during the first month of the study.

Eight horses died or were euthanized during the study due to worsening of pre-existing conditions (laminitis, dental disease, septic tenosynovitis) or colic (strangulating lipomas, large colon volvulus).

One mare was inadvertently enrolled in the study while pregnant and experienced dystocia resulting in the death of the foal.

**Post-Approval Experience (2019):**

The following adverse events are based on post approval adverse drug experience reporting for pergolide tablets.

Not all adverse events are reported. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data.

The following adverse events in horses are categorized in order of decreasing reporting frequency by body system and in decreasing order of reporting frequency within each body system:

**General:** anorexia, lethargy, weight loss

**Gastrointestinal:** diarrhea, abdominal pain/colic

**Dermatological:** alopecia, hyperhidrosis, dermatitis

**Musculoskeletal:** laminitis, muscle stiffness/soreness

**Neurological:** ataxia, seizure, muscle tremors

**Behavioral:** aggression (to other horses and humans), hyperactivity (anxiety, agitation), other behavioral changes (stud-like behavior, spooky, unpredictable, confused)

**Clinical pathology:** anemia, elevated liver enzymes, thrombocytopenia

The above adverse events were reported in some horses at starting dose levels, while in the others following a dose increase.

Death (including euthanasia) has been reported.

Adverse events have been reported in dogs following ingestion of tablets prepared for administration to horses.

**Contact Information:** To report suspected adverse reactions, to obtain a Safety Data Sheet (SDS), or for technical assistance, contact Dechra Veterinary Products at 1-866-933-2472.

For additional information about adverse drug experience reporting for animal drugs, contact the FDA at 1-888-FDA-VEIS or online at <http://www.fda.gov/reportanmae>

**Clinical Pharmacology:** Pergolide mesylate is a synthetic ergot derivative and is a potent dopamine receptor agonist. As with other dopamine agonists, pergolide inhibits the release of prolactin which suggests that it may interfere with lactation. In horses with PPID, pergolide is believed to exert its therapeutic effect by stimulating dopamine receptors, and has been shown to decrease the plasma levels of adrenocorticotropic hormone (ACTH), melanocyte stimulating hormone (MSH), and other pro-opiomelanocortin peptides.<sup>1</sup>

Pharmacokinetic information in the horse is based on a study using single oral doses of 10 mcg/kg in six healthy mares between 3 and 17 years of age. Pergolide was rapidly absorbed; the mean maximum concentration (Cmax) was 4.05±2.02 ng/mL with the median time to maximum concentration (Tmax) being 0.415 hours.

The area under the curve (AUC) was 14.08±7.46 hr·ng/mL. The mean half life (T1/2) was 5.86±3.42 hours; the mean apparent oral clearance (CL/F) was 1204 mL/kg/hr; and the mean apparent volume of distribution (V/F) was 3082±1354 mL/kg.

**Effectiveness:** An open-label, historical control, field study evaluated the effectiveness of pergolide tablets for the control of clinical signs of PPID. A total of 122 horses with PPID were enrolled in the study, 113 of which were included in effectiveness evaluations. The success of each horse was based on results of endocrinology testing (dexamethasone suppression test or endogenous ACTH test) and/or improvement in clinical signs related to PPID (hirsutism, hyperhidrosis, polyuria/polydipsia, abnormal fat distribution, and/or muscle-wasting) on the Day 180 evaluation. Based on endocrine testing and investigators' clinical assessment scores, 86 (76.1%) of the 113 evaluable cases were treatment successes.

Table 3 Proportion of Treatment Successes on Day 180	
Percent success	Lower bound: one-sided 95% confidence interval
76.1% (86/113)	68.6%

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 pergolide tablets (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 (41.6%) of the 113 horses included in the effectiveness database required a dose increase at Day 90.

Improvement was noted in scores for all clinical sign categories and in mean results for endocrine tests.

Table 4 Percent of Animals with Improvement in Clinical Signs Relative to Baseline Scores			
Clinical sign	Day 90±7 (%)	Day 180±7 (%)	
Hirsutism	32.7%	89.2%	
Hyperhidrosis	27.4%	42.3%	
Polyuria / polydipsia	31.0%	34.2%	
Abnormal fat distribution	21.2%	33.3%	
Muscle wasting	36.3%	46.0%	

Table 5 Endocrine test results (mean values)

Test	# Animals	Baseline	Day 90	Day 180
ACTH (pg/mL)	20	73.53	51.12	45.08
DST** (mcg/dL)	93	3.12	1.39	1.47

\*\* Dexamethasone suppression test: Post dexamethasone cortisol concentration

**Animal Safety:** In a six month target animal safety study healthy adult horses received pergolide tablets administered orally once daily at doses of either 0 mcg/kg, 4 mcg/kg, 6 mcg/kg, or 8 mcg/kg (0X, 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.

Pergolide treated horses 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 flunixin meglumine. Mean red blood cell counts and hemoglobin values were lower in pergolide treated groups as compared to the control group. Other hematology parameters including hematocrit, white blood cells, absolute neutrophils, and absolute lymphocytes exhibited mild, transient decreases as compared to the control group. The hematology parameters generally decreased over the first 30 to 60 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) with excursions up to 40°C (104°F).

**How Supplied:** Zygotide tablets are available in 1 mg strength - packaged 10 tablets per blister and 60 or 160 tablets per carton.

NDC 17033-907-06 - 60 tablets

NDC 17033-907-16 - 160 tablets

Approved by FDA under ANADA # 200-823.

**References:**

<sup>1</sup>Orth, D.N., Holscher, M.A., Wilson, M.G., et al. (1982) Equine Cushing's Disease: Plasma Immunoreactive Proopiomelanocortin Peptide and Cortisol Levels Basally and in Response to Diagnostic Tests. *Endocrinology*, 110(4):1430-4

<sup>2</sup>Wright A, Gehring R, Coetzee H (2008). Pharmacokinetics of pergolide in normal mares. *American College of Veterinary Internal Medicine Forum*, Abstract #36, San Antonio, TX.

**Manufactured for:**  
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# Zygotide<sup>®</sup>

(pergolide tablets)



## Important Safety Information

As with all drugs, side effects may occur. Zygotide<sup>®</sup> (pergolide tablets) is for use in horses only. Zygotide has not been evaluated in breeding, pregnant or lactating horses. Treatment with Zygotide may cause loss of appetite. Most cases are mild. If severe, a temporary dose reduction may be necessary. Weight loss, lack of energy, and behavioral changes also may be observed. Zygotide tablets should not be crushed due to the potential for increased human exposure. Pregnant or lactating women should wear gloves when administering this product. Zygotide is contraindicated in horses with hypersensitivity to pergolide mesylate or other ergot derivatives. Keep Zygotide in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose. Dogs have eaten Zygotide tablets that were placed in food intended for horses or dropped during administration of the tablets to the horses. Adverse reactions may occur if animals other than horses ingest Zygotide tablets. Refer to the prescribing information for complete details or visit [www.dechra-us.com](http://www.dechra-us.com).

