

**PRESCRIPTION ANIMAL REMEDY
KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY
READ SAFETY DIRECTIONS BEFORE OPENING OR USING**

Prascend®

1 mg Tablets for Horses



Active constituent:

1.0 mg pergolide (as pergolide mesylate)

INDICATIONS:

For the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (PPID) (Equine Cushing's Disease) in horses and ponies.

60 tablets (100 tablets, 160 tablets)

Action

Pergolide is a synthetic ergot derivative and is a potent, long-acting dopamine receptor agonist. Both in vitro and in vivo pharmacological studies have demonstrated the activity of pergolide as a selective dopamine agonist with little or no effect on norepinephrine, epinephrine or serotonin pathways at therapeutic doses. Pergolide inhibits the release of prolactin. In horses with Pituitary Pars Intermedia Dysfunction (PPID) pergolide exerts its therapeutic effect by stimulating dopamine receptors; this inhibits the production and release of adrenocorticotrophic hormone (ACTH) and alpha-melanocyte-stimulating hormone (α -MSH) from the intermediate lobe of the pituitary gland. In horses with PPID, pergolide has been shown to decrease the plasma levels of ACTH, MSH and other pro-opiomelanocortin peptides.

DIRECTIONS FOR USE

RESTRAINT: DO NOT USE in horses that may be used for human consumption.

CONTRAINDICATIONS

This product is contraindicated in horses with known hypersensitivity to pergolide mesylate or other ergot derivatives.

PRECAUTIONS

Use with caution in breeding animals and pregnant or lactating mares. Safe use in these groups has not been established and the pharmacological action of pergolide mesylate suggests that it may interfere with reproductive functions such as lactation. Use with caution in horses less than 2 years of age.

Side effects

Prascend® is well tolerated in horses. Potential adverse reactions in horses include sweating, inappetence, transient anorexia and lethargy, mild central nervous system signs (e.g. mild depression and mild ataxia), diarrhoea and colic. These signs are usually mild and transient in nature. If signs of dose intolerance develop, treatment should be stopped for 2 to 3 days and reinstated at one-half of the previous dose. The total daily dose may then be titrated back up to the desired clinical effect by 0.5 mg increments every 2 to 4 weeks.

Interaction with other medicinal products and other forms of interaction

Use with caution in cases where the product is co-administered with other drugs known to affect protein binding. Do not administer concurrently with dopamine antagonists, such as neuroleptics (phenothiazines e.g. acepromazine), domperidone, or metoclopramide, as these agents may reduce the effectiveness of pergolide.

DOSAGE AND ADMINISTRATION

The product should be administered orally, once daily. The tablet can be administered whole in a treat.

To facilitate administration, the required daily dose can be placed in a small amount of water and/or mixed with molasses or other sweetener and agitated until dissolved. In this case, the dissolved tablets should be administered with a syringe. The whole amount should be administered immediately. Tablets should not be crushed.

Starting dose

The average starting dose is 2 μ g pergolide/kg body weight, this should then be titrated according to the individual response as determined by monitoring (see below).

Starting doses are recommended as follows:

| Horse body weight | Number of tablets | Starting dose | Dosage Range |
|-------------------|-------------------|---------------|----------------------|
| 200-400 kg | ½ | 0.5 mg | 1.3 – 2.5 μ g/kg |
| 401-600 kg | 1 | 1.0 mg | 1.7 – 2.5 μ g/kg |
| 601-850 kg | 1 ½ | 1.5 mg | 1.8 – 2.5 μ g/kg |
| 851-1000 kg | 2 | 2.0 mg | 2.0 – 2.4 μ g/kg |

Maintenance dose

Life long treatment is anticipated for this disease, clinical signs will return if treatment is ceased. Most horses respond to therapy and are stabilised at an average dose of 2 μ g pergolide/kg bodyweight. Clinical improvement with pergolide is expected within 6 to 12 weeks, however, it may vary depending on the severity of disease.

Following initial diagnosis, repeat endocrinology testing such as endogenous ACTH or overnight dexamethasone suppression test (ODST) at intervals of 4 to 6 weeks until improvement of clinical signs and/or stabilisation of diagnostic testing occurs.

Clinical signs of PPID may include: hirsutism, polyuria, polydipsia, muscle wasting, abnormal fat distribution, chronic infections, laminitis and abnormal sweating.

If clinical signs do not respond adequately, the veterinarian may decide to increase the dose administered. Any increase should be titrated to consider the individual's response/tolerance to the dose and it is therefore recommended to titrate to the lowest effective dose per individual based on response to therapy.

When clinical signs or diagnostic testing are not adequately controlled, the veterinarian may decide to increase the total daily dose by 0.5 mg increments every 4 to 6 weeks until stabilisation occurs and if the drug is tolerated at that dose.

If signs of dose intolerance, such as depression, anorexia or diarrhoea develop, treatment should be stopped for 2 to 3 days and reinstated at one-half of the previous dose. The total daily dose may then be titrated back up to the desired clinical effect by 0.5 mg increments every 2 to 4 weeks, although appropriate monitoring is advised at any dose above the recommended dose of 2 µg/kg bodyweight per day.

If a dose is missed, the next scheduled dose should be administered as prescribed.

Following stabilisation, regular clinical assessment and diagnostic testing should be performed every 6 months to monitor treatment and dose. Where there is no apparent response to treatment, the diagnosis should be re-evaluated.

WITHHOLDING PERIOD

**MEAT WITHHOLDING PERIOD (HORSES):
DO NOT USE in horses that may be used for human consumption.**

SAFETY DIRECTIONS

Harmful if swallowed. Wash hands after use.

FIRST AID

If poisoning occurs contact a doctor or Poisons Information Centre.
Phone Australia 131126

DISPOSAL

Dispose of empty container by wrapping with paper and putting in garbage.

STORAGE

Store below 25°C (Air conditioning).

Presentation

Pink rectangular scored tablets in cold-formed blister pack. 10 tablets per blister in cardboard box containing 60 (100 or 160) tablets. Not all pack sizes may be marketed.

Australia

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