

Long-Term Monitoring

Once an optimum dose of VETORYL Capsules has been reached, re-examine the dog at 30 days, 90 days and every 3 months thereafter. At a minimum, this monitoring should include a thorough history and physical examination, ACTH stimulation test (conducted 4-6 hours after VETORYL Capsule administration), and serum biochemical tests (with particular attention to electrolytes, renal and hepatic function). A post-ACTH stimulation test resulting in a cortisol of <1.45 µg/dL (<40 nmol/L), with or without electrolyte abnormalities, may precede the development of clinical signs of hypoadrenocorticism. Good control is indicated by favorable clinical signs as well as post-ACTH serum cortisol of 1.45-9.1 µg/dL (40-250 nmol/L).

If the ACTH stimulation test is <1.45 µg/dL (<40 nmol/L) and/or if electrolyte imbalances characteristic of hypoadrenocorticism (hyperkalemia and hyponatremia) are found, VETORYL Capsules should be temporarily discontinued until recurrence of clinical signs consistent with hyperadrenocorticism and test results return to normal (1.45-9.1 µg/dL or 40-250 nmol/L). VETORYL Capsules may then be re-introduced at a lower dose.

Owners should be instructed to stop therapy and contact their veterinarian immediately in the event of adverse reactions or unusual developments.

CONTRAINDICATIONS:

The use of VETORYL Capsules is contraindicated in dogs that have demonstrated hypersensitivity to trilostane.

Do not use VETORYL Capsules in animals with primary hepatic disease or renal insufficiency.

Do not use in pregnant dogs. Studies conducted with trilostane in laboratory animals have shown teratogenic effects and early pregnancy loss.

WARNINGS:

In case of overdosage, symptomatic treatment of hypoadrenocorticism with corticosteroids, mineralocorticoids and intravenous fluids may be required.

Angiotensin-converting enzyme (ACE) inhibitors should be used with caution with VETORYL Capsules, as both drugs have aldosterone-lowering effects which may be additive, impairing the patient's ability to maintain normal electrolytes, blood volume and renal perfusion. Potassium sparing diuretics (e.g. spironolactone) should not be used with VETORYL Capsules, as both drugs have the potential to inhibit aldosterone, increasing the likelihood of hyperkalemia.

HUMAN WARNINGS:

Keep out of reach of children. Not for human use.

Wash hands after use. Do not empty capsule contents and do not attempt to divide the capsules. Do not handle the capsules if pregnant or if trying to conceive. Trilostane is associated with teratogenic effects and early pregnancy loss in laboratory animals. In the event of accidental ingestion/overdose, seek medical advice immediately and take the labeled container with you.

PRECAUTIONS:

Hypoadrenocorticism can develop at any dose of VETORYL Capsules. In some cases, it may take months for adrenal function to return and some dogs never regain adequate adrenal function.

A small percentage of dogs may develop corticosteroid withdrawal syndrome within 10 days of starting treatment. This phenomenon results from acute withdrawal of circulating glucocorticoids; clinical signs include weakness, lethargy, anorexia, and weight loss. These clinical signs should be differentiated from an early hypoadrenocortical crisis by measurement of serum electrolyte concentrations and performance of an ACTH stimulation test. Corticosteroid withdrawal syndrome should respond to cessation of VETORYL Capsules (duration of discontinuation based on the severity of the clinical signs) and restarting at a lower dose.

Mitotane (o,p'-DDD) treatment will reduce adrenal function. Experience in foreign markets suggests that when mitotane therapy is stopped, an interval of at least one month should elapse before the introduction of VETORYL Capsules. It is important to wait for both the recurrence of clinical signs consistent with hyperadrenocorticism, and a post-ACTH cortisol level of >9.1 µg/dL (>250 nmol/L) before treatment with VETORYL Capsules is initiated. Close monitoring of adrenal function is advised, as dogs previously treated with mitotane may be more responsive to the effects of VETORYL Capsules.

The use of VETORYL Capsules will not affect the adrenal tumor itself. Adrenalectomy should be considered as an option for cases that are good surgical candidates.

The safe use of this drug has not been evaluated in lactating dogs and males intended for breeding.



Treatment Tips

DO NOT split capsules.

DO NOT give a double dose. If a dose is missed, give the prescribed dose of VETORYL Capsules at the regular dosing time the next day.

DO NOT handle the capsules if you are pregnant or trying to conceive.

DO NOT change your dog's dose without advice from your veterinarian.

DO NOT stop giving your dog the prescribed dose of VETORYL Capsules because you notice a dramatic physical improvement. VETORYL Capsules will prevent overproduction of cortisol, but they will not cure the disease. You should only stop VETORYL Capsules if advised by your veterinarian or if your dog becomes ill.

DO wash your hands after giving VETORYL Capsules to your dog.

DO give VETORYL Capsules in the morning with food.

DO take your dog back to your veterinarian for regular monitoring.

DO note your dog's weight, water consumption, appetite, and frequency of urination before treatment so you can monitor his or her improvement following treatment.

DO take photos before you start treatment. Improvements occur gradually and are difficult to see on a daily basis.

Contact your veterinarian immediately if your dog stops eating or drinking, or becomes ill in any way while taking VETORYL Capsules.



www.VETORYL.com

VTYL-1109-01-48685

Living with Cushing's Syndrome



How to help bring back your dog's vitality.





Diagnosing the Disease

Some clinical signs of Cushing's syndrome may initially be overlooked, because they mimic normal aging changes. Keep in mind that not all dogs will react to the disease in the same way or display all of these symptoms:

- Increased water intake
- Frequent urination
- Muscle wasting/weakness
- Lethargy
- Ravenous appetite
- Pot belly
- Excessive panting
- Hair loss
- Recurring skin disease
- Thin skin

Due to the difficulty of accurately diagnosing Cushing's syndrome, special blood tests are necessary to confirm the disease. Your dog may need to spend the day with your veterinarian to complete these tests. An ultrasound examination may also be required, so that the veterinarian can differentiate between a pituitary tumor and an adrenal tumor.

The Importance of Treatment

Cushing's syndrome impacts the quality of life for both you and your dog.* If left untreated, Cushing's syndrome increases your dog's risk of developing serious conditions such as:

- Diabetes
- Blood clots in the lungs
- Kidney infection
- Urinary tract infection
- Inflammation of the pancreas



Managing Cushing's Syndrome

Cushing's syndrome can be successfully managed and controlled through medication. VETORYL® (trilostane) Capsules are the only licensed treatment for managing the clinical signs associated with both the pituitary gland and adrenal gland tumors that cause Cushing's syndrome.

With VETORYL Capsules, you and your veterinarian can effectively control the symptoms of Cushing's syndrome and help your dog maintain a good quality of life for years to come.

The First Steps to Good Health

The sooner you begin treatment of Cushing's syndrome, the sooner your dog will begin to feel better.

*Cook, AK. Trilostane: A therapeutic consideration for dogs with hyperadrenocorticism. *Veterinary Medicine*, February 2008.



Today

Your veterinarian will recommend a starting dose of VETORYL Capsules based on your dog's body weight.

In 2 weeks

Your veterinarian will assess your dog's response to VETORYL Capsule treatment by evaluating the clinical signs, performing blood tests, and possibly adjusting the dosage.

In most cases, you can expect to see the following improvements within two weeks of starting therapy with VETORYL Capsules:

- Decrease in appetite
- Increase in energy
- Decrease in water consumption
- Decrease in frequency of urination

At 4 and 12 weeks

Your veterinarian will schedule appointments to continue monitoring the early stages of therapy and, if needed, adjust the dosage of VETORYL Capsules to meet your dog's specific needs.

Every 3 months

Once your veterinarian is satisfied with your dog's progress, office visits are generally only necessary once every three months. However, your veterinarian will need to see your dog sooner if any illness arises or if the signs of Cushing's syndrome recur.



Frequently Asked Questions

Q: Why do I have to give VETORYL Capsules every day?

A: The active ingredient in VETORYL Capsules is trilostane, a short-acting drug that must be given daily to control the disease.

Q: How do I give VETORYL Capsules to my dog?

A: You should give your dog VETORYL Capsules with a meal in the morning. Food improves the absorption of VETORYL Capsules. Morning dosing makes it more convenient to schedule the monitoring tests that need to take place four to six hours after dosing.

Q: What do I do on the day of monitoring?

A: Give the prescribed dose of VETORYL Capsules at the regular time with a small amount of food.

Q: What should I do if I forget a capsule?

A: Give the prescribed dose of VETORYL Capsules at the next regular dosing time. Do not give a double dose the next day.

Q: How long will my dog need treatment?

A: Most dogs need to be given VETORYL Capsules for life.

Q: How long will it take my dog to improve after beginning treatment with VETORYL Capsules?

A: Clinical signs such as lethargy or increased drinking, eating, and urination often improve within the first two weeks of treatment. Skin changes and hair regrowth may take three to six months to improve.

Q: Will I need to revisit my veterinarian?

A: Yes. It is important for your veterinarian to supervise your dog's progress and monitor the dosage of VETORYL Capsules. Evaluations should be performed at 2 weeks, 4 weeks, and 12 weeks after starting treatment. Once on the maintenance dose, your dog should be evaluated by your veterinarian every three months.

Q: Do VETORYL Capsules have any side effects?

A: VETORYL Capsules are well tolerated by most dogs. If your dog develops any sign of illness while on VETORYL Capsules – particularly lethargy, vomiting, diarrhea, or loss of appetite – stop treatment immediately and contact your veterinarian as soon as possible.



*Following 9 months
of treatment with VETORYL*

Photographs courtesy of Carlos Melian, DVM, PhD

Too much jargon? Don't worry. We have listed some of the terms and their definitions below.

ACTH

Stands for *adrenocorticotropic hormone*. This hormone is produced by the pituitary gland and stimulates the adrenal glands to produce hormones, including cortisol.

ACTH Stimulation Test

This test is designed to measure the amount of cortisol released into the bloodstream after an injection of ACTH.

Adrenal-Dependent Hyperadrenocorticism (ADH)

This is a form of Cushing's syndrome resulting from a tumor in the adrenal glands.

Adrenal Glands

Two small glands located next to each of the kidneys that are responsible for producing hormones that help control metabolism, blood pressure, and fluid balance. Cortisol is one of the hormones released by the adrenal glands.

Cortisol

The body's natural stress-fighting and anti-inflammatory hormone.

Cushing's Syndrome

Another name for *hyperadrenocorticism*, the term given to an endocrine condition characterized by an excessive amount of cortisol being released into the body. Harvey William Cushing (1869-1939) was a pioneering neurosurgeon who gave his name to this disease. The group of clinical signs resulting from the disease is known as Cushing's syndrome.

Enzyme

A protein that triggers chemical reactions in the body.

Glucocorticoids

Also known as steroids, glucocorticoids are a group of hormones released from the adrenal glands that affect the body's metabolism. Cortisol is a glucocorticoid.

Hormones

Hormones act as chemical messengers to body organs, stimulating certain life processes and decreasing others.

Hyperadrenocorticism (HAC)

This is another name for Cushing's syndrome. It is often abbreviated as HAC.

Metabolism

The physical and chemical processes by which the body builds and maintains itself and by which it breaks down food and nutrients to produce energy.

Pituitary-Dependent

Hyperadrenocorticism (PDH)

This is a form of Cushing's syndrome resulting from a tumor in the pituitary gland.

Pituitary Gland

A gland situated at the base of the brain. The pituitary gland releases ACTH, which in turn stimulates the production and release of cortisol into the body.

Trilostane

The active ingredient in VETORYL that is known to block the production of cortisol.

VETORYL® Capsules

A drug containing the active ingredient trilostane, VETORYL Capsules were developed by Dechra Veterinary Products to treat Cushing's syndrome in dogs.



Adrenocortical suppressant for oral use in dogs only.

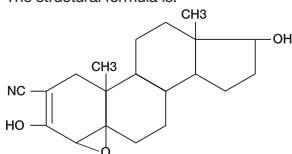
CAUTION:

Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION:

VETORYL Capsules are available in 3 sizes (10, 30 and 60 mg) for oral administration based on body weight. Trilostane (4a, 5a-epoxy-17β-hydroxy-3-oxoandrosterane-2a-carbonitrile) is an orally active synthetic steroid analogue that selectively inhibits 3β-hydroxysteroid dehydrogenase in the adrenal cortex, thereby inhibiting the conversion of pregnenolone to progesterone. This inhibition blocks production of glucocorticoids and to a lesser extent, mineralocorticoids and sex hormones while steroid precursor levels increase.

The structural formula is:



INDICATIONS:

VETORYL Capsules are indicated for the treatment of pituitary-dependent hyperadrenocorticism in dogs. VETORYL Capsules are indicated for the treatment of hyperadrenocorticism due to adrenocortical tumor in dogs.

DOSAGE AND ADMINISTRATION:

Always provide the Client Information Sheet with prescription. The starting dose for the treatment of hyperadrenocorticism in dogs is 1.0-3.0 mg/lb (2.2-6.7 mg/kg) once a day based on body weight and capsule size (see Table 1). VETORYL Capsules should be administered with food.

Table 1: Starting dose

Weight range (pounds)	Weight range (kg)	Starting dose (mg) ONCE DAILY
≥3.8 to <10	≥1.7 to <4.5	10
≥10 to <22	≥4.5 to <10	30
≥22 to <44	≥10 to <20	60
≥44 to <88	≥20 to <40	120 (2 x 60 mg)
≥88 to <132*	≥40 to <60*	180 (3 x 60 mg)

*Dogs over 132 pounds (60 kg) should be administered the appropriate combination of capsules.

After approximately 10-14 days at this dose, re-examine the dog and conduct a 4-6 hour post-dosing ACTH stimulation test. If physical examination is acceptable, take action according to Table 2.

Table 2: Action at 10-14 day evaluation

Post-ACTH serum cortisol		Action
µg/dL	nmol/L	
<1.45	<40	Stop treatment. Re-start at decreased dose
1.45 to 5.4	40 to 150	Continue on same dose
>5.4 to 9.1	>150 to 250	EITHER: Continue on current dose if clinical signs are well controlled OR: Increase dose if clinical signs of hyperadrenocorticism are still evident*
>9.1	>250	Increase initial dose

*Combinations of capsule sizes should be used to slowly increase the once daily dose.

Individual dose adjustments and close monitoring are essential. Re-examine and conduct an ACTH stimulation test 10-14 days after every dose alteration. Care must be taken during dose increases to monitor the dog's clinical signs and serum electrolyte concentrations. Once daily administration is recommended. However, if clinical signs are not controlled for the full day, twice daily dosing may be needed using combinations of capsule sizes to slowly increase the dose. For once daily doses up to 90 mg, increase the total daily dose by 30 mg and divide into 2 doses given 12 hours apart. For once daily doses ≥120 mg, increase the total daily dose by 60 mg and divide into 2 doses given 12 hours apart.

What is Cushing's Syndrome?

Cushing's syndrome is one of the most commonly diagnosed canine endocrine disorders. Dogs with this disease produce excessive amounts of cortisol, a hormone that normally helps the body respond to stress. Overproduction of cortisol can have harmful effects on your dog's internal organs and can diminish health and vitality.

Cushing's syndrome is usually caused by a tumor of either the pituitary gland or the adrenal glands.

Pituitary gland tumors account for 80-85% of Cushing's syndrome cases. These tumors cause the pituitary gland to produce large amounts of the hormone ACTH, which stimulates the adrenal gland to overproduce cortisol. Malignant tumors of the pituitary gland are rare.

Adrenal gland tumors account for 15-20% of Cushing's syndrome cases. These tumors, which can occur in either one or both adrenal glands, cause production of excessive amounts of cortisol. Surgical removal of the affected gland is sometimes recommended in these cases. Benign and malignant adrenal tumors occur with equal frequency.

ADVERSE REACTIONS:

The most common adverse reactions reported are poor/reduced appetite, vomiting, lethargy/dullness, diarrhea, and weakness. Occasionally, more serious reactions, including severe depression, hemorrhagic diarrhea, collapse, hypoadrenocortical crisis or adrenal necrosis/rupture may occur, and may result in death.

In a US field study with 107 dogs, adrenal necrosis/rupture (two dogs) and hypoadrenocorticism (two dogs) were the most severe adverse reactions in the study. One dog died suddenly of adrenal necrosis, approximately one week after starting trilostane therapy. One dog developed an adrenal rupture, believed to be secondary to adrenal necrosis, approximately six weeks after starting trilostane therapy. This dog responded to trilostane discontinuation and supportive care.

Two dogs developed hypoadrenocorticism during the study. These two dogs had clinical signs consistent with hypoadrenocorticism (lethargy, anorexia, collapse) and post-ACTH cortisol levels of $\leq 0.3 \mu\text{g/dL}$. Both dogs responded to trilostane discontinuation and supportive care, and one dog required continued treatment for hypoadrenocorticism (glucocorticoids and mineralocorticoids) after the acute presentation.

Additional adverse reactions were observed in 93 dogs. The most common of these included diarrhea (31 dogs), lethargy (30 dogs), inappetence/anorexia (27 dogs), vomiting (28 dogs), musculoskeletal signs (lameness, worsening of degenerative joint disease) (25 dogs), urinary tract infection (UTI)/hematuria (17 dogs), shaking/shivering (10 dogs), otitis externa (8 dogs), respiratory signs (coughing, congestion) (7 dogs), and skin/coat abnormality (seborrhea, pruritus) (8 dogs).

Five dogs died or were euthanized during the study (one dog secondary to adrenal necrosis, discussed above, two dogs due to progression of pre-existing congestive heart failure, one dog due to progressive central nervous system signs, and one dog due to cognitive decline leading to inappropriate elimination). In addition to the two dogs with adrenal necrosis/rupture and the two dogs with hypoadrenocorticism, an additional four dogs were removed from the study as a result of possible trilostane-related adverse reactions, including collapse, lethargy, inappetence, and trembling.

Complete blood counts conducted pre- and post-treatment revealed a statistically significant ($p < 0.005$) reduction in red cell variables (HCT, HGB, and RBC), but the mean values remained within the normal range. Additionally, approximately 10% of the dogs had elevated BUN values ($\geq 40 \text{ mg/dL}$) in the absence of concurrent creatinine elevations. In general, these dogs were clinically normal at the time of the elevated BUN.

In a long-term follow-up study of dogs included in the US effectiveness study, the adverse reactions were similar to the short-term study. Vomiting, diarrhea and general gastrointestinal signs were most commonly observed. Lethargy, inappetence/anorexia, heart murmur or cardiopulmonary signs, inappropriate urination/incontinence, urinary tract infections or genitourinary disease, and neurological signs were reported. Included in the US follow-up study were 14 deaths, three of which were possibly related to trilostane. Eleven dogs died or were euthanized during the study for a variety of conditions considered to be unrelated to or to have an unknown relationship with administration of trilostane.

In two UK field studies with 75 dogs, the most common adverse reactions seen were vomiting, lethargy, diarrhea/loose stools, and anorexia. Other adverse reactions included: nocturia, corneal ulcer, cough, persistent estrus, vaginal discharge and vulvar swelling in a spayed female, hypoadrenocorticism, electrolyte imbalance (elevated potassium with or without decreased sodium), collapse and seizure, shaking, muscle tremors, constipation, scratching, weight gain, and weight loss. One dog died of congestive heart failure and another died of pulmonary thromboembolism. Three dogs were euthanized during the study. Two dogs had renal failure and another had worsening arthritis and deterioration of appetite.

In a long-term follow-up of dogs included in the UK field studies, the following adverse reactions were seen: hypoadrenocortical episode (including syncope, tremor, weakness, and vomiting), hypoadrenocortical crisis or renal failure (including azotemia, vomiting, dehydration, and collapse), chronic intermittent vaginal discharge, hemorrhagic diarrhea, occasional vomiting, and distal limb edema. Signs of hypoadrenocorticism were usually reversible after withdrawal of the drug, but may be permanent. One dog discontinued VETORYL Capsules and continued to have hypoadrenocorticism when evaluated a year later. Included in the follow-up were reports of deaths, at least 5 of which were possibly related to use of VETORYL Capsules. These included dogs that died or were euthanized because of renal failure, hypoadrenocortical crisis, hemorrhagic diarrhea, and hemorrhagic gastroenteritis.

Foreign Market Experience: The following events were reported voluntarily during post-approval use of VETORYL Capsules in foreign markets. The most serious adverse events were death, adrenal necrosis, hypoadrenocorticism (electrolyte alterations, weakness, collapse, anorexia, lethargy, vomiting, diarrhea, and azotemia), and corticosteroid withdrawal syndrome (weakness, lethargy, anorexia, and weight loss). Additional adverse events included: renal failure, diabetes mellitus, pancreatitis, autoimmune hemolytic anemia, vomiting, diarrhea, anorexia, skin reactions (rash, erythematous skin eruptions), hind limb paresis, seizures, neurological signs from growth of macroadenomas, oral ulceration, and muscle tremors.

For a copy of the Material Safety Data Sheet (MSDS), or to report adverse reactions, call Dechra Veterinary Products at (866) 933-2472.

INFORMATION FOR DOG OWNERS:

Owners should be aware that the most common adverse reactions may include: an unexpected decrease in appetite, vomiting, diarrhea, or lethargy and should receive the Client Information Sheet with the prescription. Owners should be informed that control of hyperadrenocorticism should result in resolution of polyphagia, polyuria and polydipsia. **Serious adverse reactions associated with this drug can occur without warning and in rare situations result in death (see ADVERSE REACTIONS). Owners should be advised to discontinue VETORYL Capsules and contact their veterinarian immediately if signs of intolerance are observed.** Owners should be advised of the importance of periodic follow-up for all dogs during administration of VETORYL Capsules.

CLINICAL PHARMACOLOGY:

Trilostane absorption is enhanced by administration with food. In healthy dogs, maximal plasma levels of trilostane occur within 1.5 hours, returning to baseline levels within twelve hours, although large inter-dog variation occurs. There is no accumulation of trilostane or its metabolites over time.

EFFECTIVENESS:

Eighty-three dogs with hyperadrenocorticism were enrolled in a multi-center US field study. Additionally, 30 dogs with hyperadrenocorticism were enrolled in two UK field studies. Results from these studies demonstrated that treatment with VETORYL Capsules resulted in an improvement in clinical signs (decreased thirst, decreased frequency of urination, decreased panting, and improvement of appetite and activity). Improvement in post-ACTH cortisol levels occurred in most cases within 14 days of starting VETORYL Capsules therapy.

In these three studies, there were a total of 10 dogs diagnosed with hyperadrenocorticism due to an adrenal tumor or due to concurrent pituitary and adrenal tumors. Evaluation of these cases failed to demonstrate a difference in clinical, endocrine, or biochemical response when compared to cases of pituitary-dependent hyperadrenocorticism.

ANIMAL SAFETY:

In a laboratory study, VETORYL Capsules were administered to 8 healthy 6-month-old Beagles per group at 0X (empty capsules), 1X, 3X, and 5X the maximum starting dose of 6.7 mg/kg twice daily for 90 days. Three animals in the 3X group (receiving 20.1 mg/kg twice daily) and five animals in the 5X group (receiving 33.5 mg/kg twice daily) died between Days 23 and 46. They showed one or more of the following clinical signs: decreased appetite, decreased activity, weight loss, dehydration, soft stool, slight muscle tremors, diarrhea, lateral recumbency, and staggering gait. Bloodwork showed hyponatremia, hyperkalemia, and azotemia, consistent with hypoadrenocortical crisis. Post-mortem findings included epithelial necrosis or cystic dilation of duodenal mucosal crypts, gastric mucosal or thymic hemorrhage, atrial thrombosis, pyelitis and cystitis, and inflammation of the lungs.

ACTH stimulated cortisol release was reduced in all dogs treated with VETORYL Capsules. The dogs in the 3X and 5X groups had decreased activity. The 5X dogs had less weight gain than the other groups. The 3X and 5X dogs had lower sodium, albumin, total protein, and cholesterol compared to the control dogs. The 5X dogs had lower mean corpuscular volume than the controls. There was a dose dependent increase in amylase. Post-mortem findings included dose dependent adrenal cortical hypertrophy.

STORAGE INFORMATION:

Store at controlled room temperature 25°C (77°F) with excursions between 15°-30°C (59°-86°F) permitted.

HOW SUPPLIED:

VETORYL Capsules are available in 10, 30 and 60 mg strengths, packaged in aluminum foil blister cards of 10 capsules, with 3 cards per carton.

VETORYL Capsules 10 mg	NDC 17033-110-30
VETORYL Capsules 30 mg	NDC 17033-130-30
VETORYL Capsules 60 mg	NDC 17033-160-30

NADA 141-291, APPROVED BY FDA.

TAKE TIME  OBSERVE LABEL DIRECTIONS

Distributed by:

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'Greco DS, Behrend EN (1995) Corticosteroid withdrawal syndrome. In: Kirk's Current Veterinary Therapy XII; Bonagura, J. (ed); WB Saunders, Philadelphia PA: pp 413-5.


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