
Hyperthyroidism can take away their health.
Help restore it.
CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.
FELIMAZOLE Coated Tablets are a registered trademark of Dechra Ltd.
Dechra Veterinary Products US and the Dechra D logo are registered trademarks of Dechra Pharmaceuticals, PLC.
© 2015
01CB-FEL50034-0715
Dechra
Veterinary Products
FELIMAZOLE® Coated Tablets
(methimazole)

What is hyperthyroidism?

Cats with hyperthyroidism have a thyroid gland that is producing excessive amounts of thyroid hormones. This causes a dramatic increase in the body's metabolic rate.

A brief description

Hyperthyroidism occurs when the thyroid gland over-produces thyroid hormones. Your cat's thyroid gland is located in its neck. It is divided into two parts, called lobes, which lie on either side of the windpipe (trachea).

When a cat has hyperthyroidism, either one or both of the thyroid lobes become enlarged (both lobes are affected in 70% of cases). This leads to excessive production of the thyroid hormones T4 (also known as thyroxine) and T3 (also known as triiodothyronine).

These hormones:

- Are essential for proper growth of body cells and the development of these cells for specific roles in the body.
- Help regulate the metabolism of protein, fat and carbohydrates by cells.
- Are involved in the regulation of heat production and oxygen consumption and therefore a wide range of metabolic processes.

As a result, an excess of thyroid hormones affects the function of virtually every organ system.

What causes hyperthyroidism?

The reasons for the change in the thyroid gland are not fully known.

In 98% of cases, the enlargement of the lobe(s) is benign and non-cancerous. In these cases, diagnosis and treatment are both straightforward and successful. In the remaining 2% of cases, the enlargement is due to a malignant cancerous growth of the thyroid gland.

Whatever the cause of the enlargement, the result is the same – excess thyroid hormones are released.

Recognizing the signs of hyperthyroidism

Hyperthyroidism is most often seen in older cats.

Cats with hyperthyroidism produce thyroid hormones in excess, which leads to a dramatic increase in their metabolic rate.

As the metabolism of each cell increases they require more energy to function. This means that a cat with hyperthyroidism has to eat an exceedingly large amount of food to provide this energy.

As the condition progresses, it becomes increasingly difficult for a cat to eat enough food to provide the huge amount of energy required, so they start to lose weight. This is why the most common clinical sign in cats with hyperthyroidism is weight loss, despite a ravenous appetite.

The increased metabolic rate also causes other changes, including a rapid heart rate.

Common signs to look for

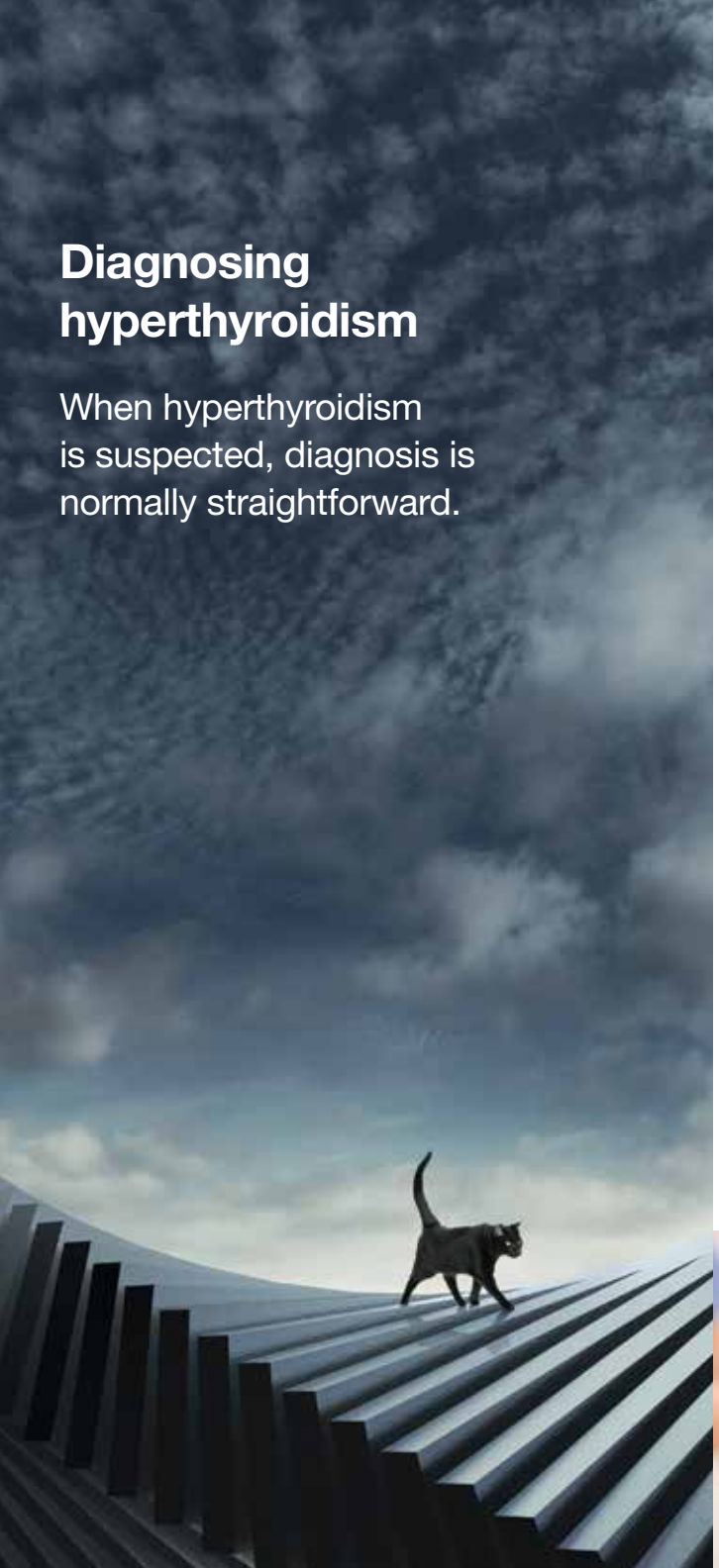
- Increased, even ravenous, appetite
- Weight loss, sometimes severe
- Increased fluid intake
- Frequent urination
- Increased restlessness and irritability
- Occasional vomiting
- Diarrhea
- An unkempt coat

Not all cats will react to the disease in the same way and your cat may not display all of these signs. Whenever possible, it is always a good idea to keep a note of the changes you see in your cat's habits, behavior and appearance.

If you become concerned about your cat's health and well-being, you should consult your veterinarian immediately.

Diagnosing hyperthyroidism

When hyperthyroidism is suspected, diagnosis is normally straightforward.



Physical examination

In some cases, your veterinarian will be able to feel the enlarged thyroid lobes in your cat's neck. Occasionally, the thyroid gland cannot be easily felt. This happens when the thyroid tissue is located elsewhere, usually inside your cat's chest.

Diagnostic tests

To confirm the diagnosis, your veterinarian will perform a blood test to measure levels of the T4 hormone. Although both the T4 and T3 hormones are produced in excess in a cat suffering from hyperthyroidism, total T4 measurement is the most accurate test available.

Since most cats with hyperthyroidism are older, your veterinarian will also recommend comprehensive blood testing and a urinalysis, to assess your cat's organ function and ensure they do not suffer from any other problems. Kidney disease, although not directly linked to hyperthyroidism, may develop at the same time since both diseases are common in older cats.

Blood tests and a urinalysis are important because other conditions might affect the successful treatment of hyperthyroidism and could also be causing harm to your cat.

What do I need to know about FELIMAZOLE Coated Tablets?

FELIMAZOLE Coated Tablets contain the active ingredient methimazole and are given to your cat every day to block the production of thyroid hormones.

The importance of treatment

Hyperthyroidism can be treated very successfully, especially since very few cats develop cancerous growths of the thyroid gland. Treatment will involve bringing the level of thyroid hormones in the blood back to normal, enabling the metabolic rate to return to normal. If left untreated, your cat may develop other serious conditions such as heart disease, commonly referred to as hypertrophic cardiomyopathy, and even high blood pressure.

Stabilization

In order to stabilize your cat's thyroid hormone levels, it is common for your veterinarian to prescribe FELIMAZOLE Coated Tablets for an initial period of three weeks.

Your veterinarian will then assess and monitor your cat's response to therapy and discuss the most suitable long-term treatment option. Always advise your veterinarian of any changes you notice with your cat once they begin therapy.

Long-term medical treatment

If your cat's hyperthyroidism is treated using FELIMAZOLE Coated Tablets, this will not cure the condition. Your cat will need to be treated for the rest of its life.

If your veterinarian recommends long term use of FELIMAZOLE Coated Tablets, monitoring of their condition is very important. Your cat will need to have regular blood tests. These tests will ensure that your cat is receiving the correct amount of medication. Routine blood tests will also allow your veterinarian to make sure your cat remains as healthy as possible as it gets older.

What you can expect

The sooner your cat begins treatment, the sooner your cat will get relief from the clinical signs of hyperthyroidism.

Today:

Begin treating your cat's hyperthyroidism with FELIMAZOLE Coated Tablets as per your veterinarian's instructions.

In 3 weeks:

Your veterinarian will assess your cat's response to FELIMAZOLE Coated Tablets by evaluating the clinical signs and performing blood tests. Your veterinarian may adjust the dose at this time.

In 6 weeks:

You will schedule an appointment with your veterinarian to continue monitoring the early stages of therapy and, if needed, make adjustments in the dosage of FELIMAZOLE Coated Tablets.

In most cases, within 3 to 6 weeks of starting therapy with FELIMAZOLE Coated Tablets, you can expect to see the following improvements:

- Decrease in excessive appetite
- Decrease in hyperactivity
- Decrease in anxiousness
- Decrease in water consumption
- Decrease in urination
- Decrease in vomiting and diarrhea
- Improved hair coat

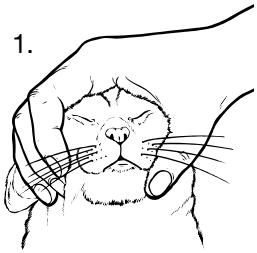
Ongoing:

Once you and your veterinarian are happy with your cat's progress, your veterinarian will establish an ongoing monitoring schedule. However, you should call your veterinarian if the clinical signs of hyperthyroidism recur or if your cat becomes ill.

How to give your cat a FELIMAZOLE Coated Tablet

1. Gently, but firmly, grasp your cat's head. If you are right-handed use your left hand; if you are left-handed use your right hand. Place your palm on their head. Put your thumb and forefinger on the side of its face, just behind its jaw. The cat's cheek-bones allow you to hold the head firmly without causing discomfort. Avoid holding the lower jaw and don't squeeze the throat. The tips of your thumb and index finger should be positioned at opposite corners of the mouth on the cat's upper gum line.

1.

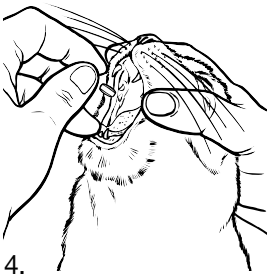


2.

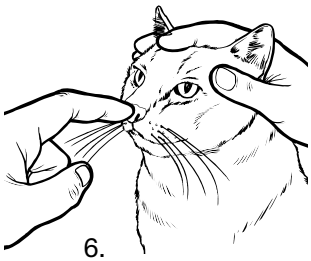
2. Gently tilt the head back so the eyes are facing upward and the nose is pointing towards the ceiling. The mouth should naturally start to open. If the cat does not open its mouth, you can ease the mouth open by squeezing your thumb and finger together and applying gentle pressure at the corners of the mouth.

3. Place the pill between the thumb and forefingers of your other hand. Use your ring finger or middle finger, open your cat's mouth further by applying pressure on the front of the lower jaw (bottom front teeth). Cats have no strength in the lower jaw in this position and cannot bite.

4. After the mouth is fully open, place the pill as far back in the mouth as possible. The "target" is the v-shaped area at the back of the throat where the tongue meets the roof of the mouth. Continue to keep the cat's head pointed upwards.



4.



6.

5. Once the pill is positioned in the back of the mouth, it is unlikely the cat will spit it out. If the pill gets under the tongue or onto the side of the mouth, the cat may spit it back out.

6. Close your cat's mouth and hold it closed. Gently blow a puff of air in your cat's nose or rub their throat. This stimulates your cat to lick its nose, causing it to swallow. If this does not work, tilt their head back a little and try again.

7. Let go and watch the cat for a few moments to make sure it doesn't spit out the pill. If it does spit out the pill, throw it away and start again. Also watch for lip licking motions which usually indicate that the pill has been swallowed. Wash hands when done.

8. Don't let your cat make a hasty exit once it has had the pill. Praise your cat and give it a treat, a favorite canned food or play with a favorite toy. Make the pill-taking just a small part of an otherwise positive experience and you'll find your cat is more cooperative the next time it is given a pill.

What to do if you're still having trouble giving your cat a FELIMAZOLE Coated Tablet

In the majority of cases, following the previous steps will allow you to successfully give a FELIMAZOLE Coated Tablet to your cat. However if you are still finding it difficult to get your cat to take the pill, you may find the following hints helpful:

1. Ask your veterinarian about coatings or "pockets" that you can cover the pill with. FELIMAZOLE Coated Tablets have a sugar coating on them, so they generally do not taste bad to the cat, but some cats prefer other flavorings.

2. Have a friend hold your cat's front legs and chest to keep it still while you concentrate on administering the pill. If you're pilling the cat yourself, hold the cat so that it can't back away. A corner works well. Or kneel down, turn the cat so that it faces away from you, and cradle it gently between your knees so you have both hands free.

3. You can also try wrapping your cat snugly in a blanket or towel so that only the head protrudes. Take care to tuck in all four legs and paws. There are several brands of professional "Cat Sacs" available that you can use. With these you can zip the cat into a bag and leave only its head peeking out. If you are having difficulties, it also helps to get some professional advice from your veterinarian's staff. They are generally experts at medicating cats.

4. Although FELIMAZOLE Coated Tablet are best given directly to your cat, you can try hiding the pill in food. However you should watch your cat so you can be sure they have actually taken the pill. Some cats will eat the food and spit out the pill. Alternatively, hide the pill in a small amount of food and offer it as a treat before feeding your cat its regular meal.

Continuous care

Your cat will need to be carefully monitored and returned for follow-up appointments on a regular basis.

A series of blood tests will need to be carried out before starting treatment, and after 3 weeks and 6 weeks of treatment, and then every three months thereafter. Your veterinarian may also recommend repeating bloodwork after any change in dosing.

Assessing the response to treatment in this way enables the veterinarian to ensure the dose of FELIMAZOLE Coated Tablets is appropriate, monitor for possible side-effects to FELIMAZOLE Coated Tablet therapy, and check for the development of any unrelated complications.

After these initial appointments and once your veterinarian is happy that your cat is stable, you will normally just need to visit every three months for monitoring of your cat's condition. Over time it may be necessary for your veterinarian to adjust the dose of FELIMAZOLE Coated Tablets prescribed.

FELIMAZOLE Coated Tablets will resolve the outward signs of hyperthyroidism while your cat is being treated but they will not cure the disease. Even if you notice dramatic physical improvements to your cat's health this does not mean you should stop treatment.

Quick reference guide

Answers to some questions you may have about FELIMAZOLE Coated Tablets

What are FELIMAZOLE Coated Tablets and how do they work?

FELIMAZOLE Coated Tablets contain the anti-thyroid drug methimazole, which inhibits the production of T4 and T3 within the thyroid gland.

How do I give FELIMAZOLE Coated Tablets to my cat?

Follow the instructions given by your veterinarian. FELIMAZOLE Coated Tablets are best given directly to your cat, but the small, sugar-coated tablets can also be hidden in the food.

What should I do if I forget to give a tablet?

Speak to your veterinarian. DO NOT give a double dose next time. If your cat is due to have a monitoring blood test within a couple of days of missing a tablet, MAKE SURE YOU LET YOUR VETERINARIAN KNOW as it could affect the blood results.

How long will my cat require treatment?

To maintain the inhibition of T4 and T3, your cat will need to be dosed with FELIMAZOLE Coated Tablets every day for the rest of their life or until your veterinarian recommends stopping it for other reasons.

Will I need to revisit my veterinarian?

Yes. It is important that your cat revisits your veterinarian for assessment and monitoring tests. These are recommended after 3 weeks and 6 weeks of treatment, and then every three months thereafter. Your veterinarian may also recommend repeating bloodwork after any change in dosing.

Do FELIMAZOLE Coated Tablets have any side-effects?

As with all drugs, side effects may occur. The most commonly reported side effects are anorexia, vomiting, head/facial pruritus (itching) or edema (swelling), depression/lethargy, weight loss, anemia, elevated liver enzymes, skin lesions, elevated BUN (kidney enzyme), diarrhea, and thrombocytopenia (low platelet levels). In some reported cases, the patients recovered after adverse signs were recognized, the drug was withdrawn, and veterinary care was applied. In some cases, death (or euthanasia) has been reported as an outcome of the adverse reactions listed above. If you notice any signs of your cat becoming ill, stop administering the medication and consult your veterinarian as soon as possible.

FELIMAZOLE Coated Tablets are a prescription only medicine and should only be used under the advice of a licensed veterinarian. It is important that you follow the instructions given by your veterinarian.

Do:

- Take your cat back to your veterinarian for regular monitoring.
- Contact your veterinarian immediately if your cat stops eating or becomes ill while on FELIMAZOLE Coated Tablets.
- Wash hands with soap and water after using FELIMAZOLE Coated Tablets or after handling litter used by treated animals.
- Wear gloves when handling litter of treated cats if you are a woman of child-bearing age or are pregnant. Wear gloves when handling FELIMAZOLE Coated Tablets if you are pregnant or lactating.

Don't:

- Change the dose without advice from your veterinarian
- Eat, drink or smoke while handling tablets or used litter
- Crush tablets

Ensure you continue giving your cat the prescribed dose of FELIMAZOLE Coated Tablets every day. Even if you notice dramatic physical improvements to your cat's health this does not mean you should stop treatment. FELIMAZOLE Coated Tablets will resolve outward signs of hyperthyroidism while your cat is being treated but they will not cure the disease.

Monitoring is important and regular checks performed by your veterinarian will ensure your cat continues to get the best possible care.

Helping you help your pet

Now that your cat has been diagnosed with hyperthyroidism it is important to follow a strict treatment and monitoring plan.

The treatment and monitoring plan has been established following an extensive trial program and is designed to optimize the management of hyperthyroidism, helping to ensure your cat enjoys a good quality of life.

Use the page opposite to keep a note of the changes you see in your cat's habits, behavior and appearance.

With daily medication and careful monitoring your cat will show improvement within 21 days. Many of the signs associated with hyperthyroidism with begin to subside and can be kept under control.

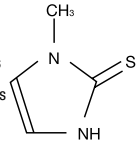
Check-up	Date	Notes
Day 1 Enter start date of treatment		
Week 3		
Week 6		
Quarterly check-up		
Quarterly check-up		
Quarterly check-up		
Quarterly check-up		

FELIMAZOLE® Coated Tablets
(methimazole)

For oral use in cats only.

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

DESCRIPTION: Methimazole is a thioureylene antithyroid drug, which inhibits the synthesis of thyroid hormones. Methimazole (1-methylimidazole-2-thiol) is a white, crystalline substance that is freely soluble in water. The chemical formula is $C_4H_6N_2S$. Molecular weight is 114.16.



Methimazole Chemical Structure

INDICATION: FELIMAZOLE Coated Tablets (methimazole) are indicated for the treatment of hyperthyroidism in cats.

DOSAGE AND ADMINISTRATION: The starting dose of FELIMAZOLE Coated Tablets is 2.5 mg administered every 12 hours. Following 3 weeks of treatment, the dose should be titrated to effect based on individual serum total T4 (TT4) levels and clinical response. Dose adjustments should be made in 2.5 mg increments. The maximum total dosage is 20 mg per day divided, not to exceed 10 mg as a single administration.

Hematology, biochemistry, and TT4 should be evaluated prior to initiating treatment and monitored after 3 weeks and 6 weeks of treatment. Thereafter, bloodwork should be monitored every 3 months and the dose adjusted as necessary. Cats receiving doses greater than 10 mg per day should be monitored more frequently.

CONTRAINDICATIONS: Do not use in cats with hypersensitivity to methimazole, carbimazole or the excipient, polyethylene glycol.
Do not use in cats with primary liver disease or renal failure.
Do not use in cats with autoimmune disease. See ADVERSE REACTIONS.
Do not use in cats with hematological disorders (such as anemia, neutropenia, lymphopenia, or thrombocytopenia) or coagulopathies. See ADVERSE REACTIONS.
Do not use in pregnant or lactating queens. Laboratory studies in rats and mice have shown evidence of teratogenic and embryotoxic effects of methimazole.

WARNINGS: Methimazole has anti-vitamin K activity and may induce bleeding diathesis without evidence of thrombocytopenia. See ADVERSE REACTIONS.

HUMAN WARNINGS: Not for use in humans. Keep out of reach of children. For use in cats only. Wash hands with soap and water after administration to avoid exposure to drug. Do not break or crush tablets. Wear protective gloves to prevent direct contact with litter, feces, urine, or vomit of treated cats, and broken or moistened tablets. Wash hands after contact with the litter of treated cats.

Methimazole is a human teratogen and crosses the placenta concentrating in the fetal thyroid gland. There is also a high rate of transfer into breast milk. Pregnant women or women who may become pregnant, and nursing mothers should wear gloves when handling tablets, litter or bodily fluids of treated cats.

Methimazole may cause vomiting, gastric distress, headache, fever, arthralgia, pruritus, and pancytopenia. In the event of accidental ingestion/overdose, seek medical advice immediately and show the product label to the physician.

PRECAUTIONS: Use of FELIMAZOLE Coated Tablets in cats with renal dysfunction should be carefully evaluated. Reversal of hyperthyroidism may be associated with decreased glomerular filtration rate and a decline in renal function, unmasking the presence of underlying renal disease. Due to potentially serious adverse reactions such as hepatopathy, immune-mediated anemia, thrombocytopenia, and agranulocytosis, cats on methimazole therapy should be monitored closely for any sign of illness including anorexia, vomiting, head/facial pruritus or edema, depression/lethargy, weight loss, anemia, skin lesions, diarrhea, fever, or lymphadenopathy. If a cat becomes ill while on FELIMAZOLE Coated Tablets, the drug should be stopped and appropriate hematological and biochemical testing should be done (see ANIMAL SAFETY and POST APPROVAL EXPERIENCE).

Anticoagulants may be potentiated by the anti-vitamin K activity of FELIMAZOLE Coated Tablets. Concurrent use of phenobarbital may reduce the clinical effectiveness of FELIMAZOLE Coated Tablets. A reduction in dose of certain drugs (β-adrenergic blocking agents, digitalis glycosides, and theophylline) may be needed when the patient becomes euthyroid.

Methimazole is known to reduce the hepatic oxidation of benzimidazole anthelmintics (e.g. fenbendazole), leading to increased plasma concentration of these anthelmintics when administered concurrently. FELIMAZOLE Coated Tablets caused delayed maturation of the testes in young male cats in the 12-week safety study. See ANIMAL SAFETY. The safety of FELIMAZOLE Coated Tablets has not been evaluated in male cats intended for breeding.

ADVERSE REACTIONS: In a US field study with 113 cats, the most common adverse reactions included change in food consumption (increase or decrease), lethargy, vomiting, diarrhea/loose stool, skin lesions, and abnormal vocalization. Three cats were withdrawn early from the study, one due to unmasking of latent renal disease and two due to the development of skin lesions. Over the course of the study, there was a decreasing trend in the mean counts of red blood cells, lymphocytes, neutrophils and monocytes; however, means remained within or near normal ranges for the testing laboratory.

In the extended use phase of the US field study with 101 cats, the most common adverse reactions reported in the study above (lethargy, anorexia) were also observed. Additional signs occurring more frequently in the long-term study were: depression/withdrawn behavior, weight loss, haircoat abnormalities, increased blood urea nitrogen (BUN), weakness, agitation and diarrhea. Most of the adverse reactions reported were mild and transient.

Serum chemistry and hematology results in the extended use study were consistent with the trends noted during the field study. The mean alanine transaminase (ALT) was above the reference range at the first two quarterly visits, but within the normal reference range (10-100 U/L) through the next two quarterly visits.

Mean lymphocyte counts decreased consistently during the study period, to slightly below the reference range (1200-8000 cells/mcL) at the fourth quarterly visit.

Sixteen cats experienced elevated antinuclear antibody (ANA) titers at one or more points during long-term therapy with FELIMAZOLE Coated Tablets, but the significance was not determined. Eighteen cats died or were euthanized during the extended use study, four of which may have been related to FELIMAZOLE Coated Tablets due to the unmasking/acceleration of chronic renal failure. See PRECAUTIONS.

In a foreign field study with 26 cats using a starting dose of 5 mg twice daily (twice the recommended starting dose), one cat was withdrawn due to lethargy, vomiting and facial excoriations. Marked thrombocytopenia was reported in two cats; the platelet count returned to normal in one cat when FELIMAZOLE Coated Tablets were discontinued. Two cats collapsed and died within 12 days of starting FELIMAZOLE Coated Tablets at a dose of 5 mg twice daily. Both cats were reported with lethargy, vomiting, anorexia, and bloody diarrhea; one cat also had pallor.

In a second foreign field study with 78 cats using a starting dose of 2.5 mg twice daily, 4 cats were withdrawn due to suspected adverse reactions to FELIMAZOLE Coated Tablets including anemia, cholangiohepatitis, excoriations, vomiting, lethargy, jaundice, and anorexia. One cat receiving 2.5 mg three times daily collapsed and died after 8 weeks of treatment. Adverse reactions included pallor, anorexia, dehydration, jaundice, bleeding diathesis, and anemia. The most frequently reported adverse reactions included mild, transient, self-limiting vomiting, lethargy, and anorexia.

Foreign Market Experience: The following events were reported voluntarily during post-approval use of FELIMAZOLE Coated Tablets in foreign markets: facial pruritus, self-induced excoriations of the head and neck, generalized lymphadenopathy, thrombocytopenia, hematemesis, epistaxis, and elevation of serum liver enzymes and bilirubin.

If overdosage occurs, stop treatment and give symptomatic and supportive care.

CLINICAL PHARMACOLOGY: Methimazole is an antithyroid drug that acts by blocking the biosynthesis of thyroid hormone in vivo. The primary action is to inhibit binding of iodide to the enzyme thyroid peroxidase, thereby preventing the catalyzed iodination of thyroglobulin and T3 and T4 synthesis.

FELIMAZOLE Coated Tablets are well absorbed following oral administration. Maximum plasma concentrations are achieved within 1-1½ hours after dosing and methimazole is rapidly eliminated from the blood (T½ is approximately 3 hours). Administration of FELIMAZOLE Coated Tablets in a fasted state enhances absorption.

EFFECTIVENESS: In a US effectiveness field study with 113 cats, the product was considered effective if both the TT4 concentration was ≤ 4.0 mcg/dL, and the Investigator's clinical assessment documented clinical improvement. Of the 105 evaluable cases, 64 (61%) were considered treatment successes. The decrease in TT4 concentration was significant from the pre-enrollment visit to the Day 42 visit. A TT4 of ≤ 4.0 mcg/dL occurred in 59.1% and 61.9% of cats on Day 21 and Day 42, respectively. Investigators assessed 91.8% and 87.6% of cats as clinically improved on Days 21 and 42, respectively.

In the extended use phase of the US effectiveness field study with 101 cats, effectiveness was based on a combination of Investigator's clinical assessment, maintenance of TT4 concentrations at or near the laboratory reference range of 0.8-4.0 mcg/dL, and the presence or absence of adverse reactions. Mean TT4 concentrations were within or near the laboratory reference range during the first four quarterly visits. At the first quarterly visit, Investigators categorized 80.9% of cats as stable or improved relative to their baseline assessment. By the fourth quarterly visit, 75.8% were deemed to be stable or improved.

The average maintenance dose required in the extended use phase was 2.5 mg twice daily, with a minimum of 2.5 mg per cat and a maximum of 15 mg per cat on a daily basis.

ANIMAL SAFETY: ANIMAL SAFETY STUDIES: In a 12-week safety study, healthy young cats were dosed with 0, 10, 20, and 30 mg FELIMAZOLE Coated Tablets per day, divided into two doses. Cats in all treated groups experienced anorexia, vomiting, loose stool and lethargy. Cats in the 20 and 30 mg/day groups also had facial excoriations, pruritus, and lymphadenopathy. The following hematological changes were seen: neutropenia, lymphopenia, anemia, and thrombocytopenia. The following biochemical changes were seen: increased globulin, increased magnesium, increased blood urea nitrogen, increased creatinine and decreased phosphorus. There was a dose-dependent occurrence of antinuclear antibodies. Most of the clinical pathology changes were mild in nature. One cat dosed with 20 mg/day experienced a six-fold increase in ALT during the study. This cat had loose stool, but was otherwise healthy throughout the study. Hepatomegaly was seen in this cat at necropsy and the histopathological examination was comparable to other treated cats with hepatomegaly and normal ALT.

Gross necropsy findings in all treated groups included hepatomegaly, thymus atrophy and thyroid hyperplasia and darkening. Some treated males had delayed maturation of the testes.

The 30 mg/day dose was poorly tolerated and resulted in the clinical deterioration and euthanasia of four of the six cats in that group. Two of the cats showed signs of immune-mediated hemolytic anemia, thrombocytopenia and severe clinical deterioration. One had been on the drug for 34 days, the other for 9 weeks. The drug was discontinued in a third cat treated with 30 mg/day while it received supportive care. It was euthanized on day 55 after becoming anorexic. This cat had anemia (HCT 21.6%) and red blood cell agglutination. Necropsy showed inflammation of the muscular layer of the stomach and a small erosion in the stomach. A fourth cat treated with 30 mg/day was euthanized after several days of anorexia when the decision was made to discontinue dosing in this group. All 30 mg/day cats that died had generalized lymphadenopathy. Necropsies revealed reactive lymph nodes and varying degrees of inflammation throughout the body. The remaining 2 cats in the 30 mg/day group were taken off FELIMAZOLE Coated Tablets at week 9 and fully recovered.

POST APPROVAL EXPERIENCE (revised 2015): The following adverse events are based on voluntary, post approval reporting. Not all adverse events are reported to FDA/CVM. 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 are listed in decreasing order of reporting frequency: Anorexia, vomiting, head/facial pruritus or edema, depression/lethargy, weight loss, anemia, elevated liver enzymes, skin lesions, elevated BUN, diarrhea, and thrombocytopenia. In some reported cases, the patients recovered after adverse signs were recognized, the drug was withdrawn, and veterinary care was applied. In some cases, death (or euthanasia) has been reported as an outcome of the adverse reactions listed above.

To report suspected adverse drug events, contact Dechra Veterinary Products at (866) 933-2472. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS, or http://www.fda.gov/AnimalVeterinary/SafetyHealth.

STORAGE INFORMATION: Store at controlled room temperature 25°C (77°F) with excursions between 15°-30°C (59°-86°F) permitted. Keep the container tightly closed in order to protect from moisture.

HOW SUPPLIED: FELIMAZOLE Coated Tablets are available in 2.5 mg or 5 mg in bottles containing 100 tablets.

NADA 141-292, Approved by FDA.
Distributed by: Dechra Veterinary Products
7015 College Boulevard, Suite 525, Overland Park, KS 66211
For a copy of the Material Safety Data Sheet (MSDS) or to report adverse reactions call Dechra Veterinary Products at (866) 933-2472.

Dechra
Veterinary Products