PARTICULARS TO APPEAR ON THE OUTER PACKAGE
30 ml Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thiamapet 10 mg/ml oral solution for Cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 10 mg of thiamazole

3. PACKAGE SIZE

30 ml

4. TARGET SPECIES

Cats

5. INDICATION(S)

For the stabilisation of hyperthyroidism in cats prior to surgical thyroidectomy.
For the long-term treatment of feline hyperthyroidism.

6. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 3 months
Once broached use by ….

9. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in the outer carton.
Keep the container tightly closed.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

14. MARKETING AUTHORISATION NUMBERS

Vm 32742/5006

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Thiamapet may cause harm to the unborn child. If you are pregnant, think you may be pregnant or are attempting to conceive, you should not administer the product or handle the litter/vomit of treated cats. Woman of child bearing age must wear gloves.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V (‘To be supplied only on veterinary prescription’)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

30ml Immediate label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thiamapet 10 mg/ml oral solution for Cats

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Thiamazole 10 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 3 months
Once broached use by ….

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

30 ml

6. ROUTE(S) OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thiamapet 10 mg/ml Oral Solution for Cats

2. COMPOSITION

Each ml contains:

Active substance:
Thiamazole 10 mg

Clear, colourless to pale yellow, homogeneous solution

3. TARGET SPECIES

Cats

4. INDICATIONS FOR USE

For the stabilisation of hyperthyroidism in cats prior to surgical thyroidectomy.
For the long-term treatment of feline hyperthyroidism.

5. CONTRAINDICATIONS

Do not use in cats suffering from systemic disease such as primary liver disease or diabetes mellitus.
Do not use in cats showing signs of autoimmune disease such as anaemia, multiple inflamed joints, skin ulceration and crusting.
Do not use in animals with disorders of white blood cells, such as neutropenia and lymphopenia. Symptoms may include lethargy and increased susceptibility to infection.
Do not use in animals with platelet disorders and coagulopathies (particularly thrombocytopenia). Symptoms may include bruising and excessive bleeding from wounds.
Do not use in cats with hypersensitivity to thiamazole or to any of the excipients.
Do not use in pregnant or lactating females.

6. SPECIAL WARNING(S)

Special warnings for each target species:
In order to enhance stabilisation of the hyperthyroid patient the same feeding and dosing schedule should be used daily.

Special precautions for use in animals:
Cats should always have access to drinking water.
Please inform the veterinarian if your cat has kidney problems.
If your cat suddenly appears unwell during treatment, particularly if s/he is febrile (has a high temperature), s/he should be examined by a veterinarian as soon as possible and have a blood sample taken for routine haematology.

Information for the treating veterinarian:
If more than 10 mg per day is required animals should be monitored particularly carefully.
Use of the product in cats with renal dysfunction should be subject to careful risk:benefit assessment by the clinician. Due to the effect thiamazole can have on reducing the glomerular filtration rate, the effect of therapy on renal function should be monitored closely as deterioration of an underlying condition may occur.
Haematology must be monitored due to risk of leucopenia or haemolytic anaemia.
Any animal that suddenly appears unwell during therapy, particularly if they are febrile, should have a blood sample taken for routine haematology and biochemistry. Neutropenic animals (neutrophil counts <2.5 x 109/l) should be treated with prophylactic bactericidal antibacterial drugs and supportive therapy.
Please refer to section “Dosage for each species, routes and method of administration/Additional information for the treating veterinarian” for monitoring instructions.
As thiamazole can cause haemoconcentration, cats should always have access to drinking water.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity (allergy) to thiamazole, glycerol, sorbitol or vanillin should avoid contact with the veterinary medicinal product. If allergic symptoms develop, such as a skin rash, swelling of the face, lips or eyes or difficulty in breathing, you should seek medical attention immediately and show the package leaflet or label to the doctor.
Thiamazole may cause gastrointestinal disturbances, headache, fever, joint pain, pruritus (itching) and pancytopaenia (decrease in blood cells and platelets).
To prevent a child consuming the product, do not leave a filled syringe unattended.
Following administration of the product any residual product remaining on the tip of the dosing syringe should be wiped clean with a tissue. The contaminated tissue should be immediately disposed of.
The used syringe should be stored with the product in the original carton.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
This product may cause eye irritation.
Avoid skin and eye exposure including hand-to-eye and hand-to mouth contact.
Do not eat, drink or smoke while handling the product or used litter.
Wash hands with soap and water after administration of the product and handling the vomit of, or litter used by, treated animals. Wash any spillages or splatter from skin immediately.
In case of accidental eye contact, rinse eyes immediately with clean running water. If irritation develops, seek medical advice.
As thiamazole may cause harm to the unborn child, women of child-bearing age must wear non-permeable single use gloves when administering the product or handling the litter/vomit of treated cats.
If you are pregnant, think you may be pregnant or are attempting to conceive, you should not administer the product or handle the litter/vomit of treated cats.
For animal treatment only.
Keep out of the sight and reach of children.

Pregnancy and lactation:
Do not use in pregnant or lactating females.
Additional information for the treating veterinarian:
Laboratory studies in rats and mice have shown evidence of teratogenic and embryotoxic effects of thiamazole. The safety of the product was not assessed in pregnant or lactating cats.

Interaction with other medicinal products and other forms of interaction:
Please inform the veterinarian if your cat is receiving any other medicines or if your cat is going to be vaccinated.
Information for the treating veterinarian:
Concurrent treatment with phenobarbital may reduce the clinical efficacy of thiamazole.
Thiamazole is known to reduce the hepatic oxidation of benzimidazole wormers and may lead to increases in their plasma concentrations when given concurrently.
Thiamazole is immunomodulatory, therefore this should be taken into account when considering vaccination programmes.

Overdose (symptoms, emergency procedures, antidotes):
If you think you have given your cat more than you should (an overdose), stop treatment and contact your veterinarian who may need to give symptomatic and supportive care.
For signs of overdose, please refer to the “Adverse reactions” section of this package leaflet.

Information for the treating veterinarian:
In tolerance studies in young healthy cats, the following dose-related clinical signs occurred at doses of up to 30 mg/animal/day: anorexia, vomiting, lethargy, pruritus and haematological and biochemical abnormalities such as neutropenia, lymphopenia, reduced serum potassium and phosphorus levels, increased magnesium and creatinine levels and the occurrence of anti-nuclear antibodies. At a dose of 30 mg/day some cats showed signs of haemolytic anaemia and severe clinical deterioration. Some of these signs may also occur in hyperthyroid cats treated at doses of up to 20 mg per day.
Excessive doses in hyperthyroid cats may result in signs of hypothyroidism. This is however unlikely, as hypothyroidism is usually corrected by negative feedback mechanisms. Please refer to Section “Adverse reactions”.
If overdosage occurs, stop treatment and give symptomatic and supportive care.

Major Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. ADVERSE EVENTS

Adverse reactions have been reported following long term control of hyperthyroidism. In many cases, signs may be mild and transitory and not a reason for withdrawal of treatment. The more serious effects are mainly reversible when medication is stopped.
Following long-term treatment with thiamazole in rodents, an increased risk of neoplasia in the thyroid gland has been shown to occur, but no evidence is available in cats.

Cats:

Uncommon (1 to 10 animals / 1,000 animals treated):	Vomiting* Inappetence/anorexia*, lethargy*, bleeding diathesis and icterus (associated with hepatopathy)* Severe pruritus and excoriations of the head and neck* Haematological abnormalities (eosinophilia, lymphocytosis, neutrophilia, lymphopaenia, slight leukopaenia, agranulocytosis, thrombocytopaenia, haemolytic anaemia)* Immune-mediated haemolytic anaemia**
Rare (1 to 10 animals / 10,000 animals treated):	Immune-mediated thrombocytopenia**, serum anti-nuclear antibodies**
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Lymphadenopathy**

*These side effects resolve within 7-45 days after cessation of thiamazole therapy.
**Treatment should be stopped immediately and alternative therapy considered following a suitable period for recovery.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system (https://www.gov.uk/report-veterinary-medicine-problem).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral use.
The product should be administered directly into the mouth of the cat. Do not administer in food as efficacy of the product when administered via this route has not been established.

For the stabilisation of feline hyperthyroidism prior to surgical thyroidectomy and for the long term treatment of feline hyperthyroidism, the recommended starting dose is 5 mg per day.

The total daily dose should be divided into two and administered morning and evening. In order to enhance stabilisation of the hyperthyroid patient the same dosing schedule relative to feeding should be used daily.

Additional information for the treating veterinarian:
Haematology, biochemistry and serum total T4 should be assessed before initiating treatment and after 3 weeks, 6 weeks, 10 weeks, 20 weeks, and thereafter every 3

months. At each of the recommended monitoring intervals, the dose should be titrated to effect according to the total T4 and to clinical response to treatment. Standard dose adjustments should be made in increments of 2.5 mg (0.25 ml of the product) and the aim should be to achieve the lowest possible dose rate. In cats that require particularly small dose adjustments, increments of 1.25 mg of thiamazole (0.125 ml of the product) can be used. If total T4 concentration drops below the lower end of the reference interval, and particularly if the cat is showing clinical signs of iatrogenic hypothyroidism (e.g. lethargy, inappetence, weight gain and/or dermatological signs such as alopecia and dry skin), consideration should be given to reducing the daily dosage and/or dosing frequency.

If more than 10 mg per day is required animals should be monitored particularly carefully.
The dose administered should not exceed 20 mg per day.

For long-term treatment of hyperthyroidism, the animal should be treated for life.

In order to enhance stabilisation of the hyperthyroid patient the same feeding and dosing schedule should be used daily.

9. ADVICE ON CORRECT ADMINISTRATION

Follow the dosing instructions and duration of treatment advised by the veterinary surgeon.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions.
Keep the container tightly closed.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening of the container: 3 months.
When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

The medicinal product is available in 30 ml presentation and an oral syringe of 1.0 ml is provided as dosing device.
Vm 32742/5006

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

Manufacturer responsible for batch release:

Lelypharma B.V.
Zuiveringweg 42
8243 PZ
Lelystad
The Netherlands

17. OTHER INFORMATION

For animal treatment only.

Information for the treating veterinarian:

Pharmacodynamic properties

Thiamazole 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 catalysed iodination of thyroglobulin and T3 and T4 synthesis.

Pharmacokinetic particulars

Following oral dosing in healthy cats, thiamazole is rapidly and completely absorbed with a bioavailability of >75 %. However, there is a considerable variation between animals. Elimination of the drug from cat plasma is rapid with a half-life of 2.6-7.1 hours. Peak plasma levels occur within a maximum of 1 hour after dosing. C_{max} is 1.6 ± 0.4 µg/ml.
In rats thiamazole has been shown to be poorly bound to plasma protein (5 %); 40 % was bound to red blood cells. The metabolism of thiamazole in cats has not been investigated, however, in rats thiamazole is rapidly metabolized. For man and rats, it

is known that the drug can cross the placenta and concentrates in the foetal thyroid gland. There is also a high rate of transfer into breast milk.

Approved 02 January 2024