

## **LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Thyroxanil 200 microgram tablets for dogs and cats  
levothyroxine sodium



**2. STATEMENT OF ACTIVE SUBSTANCES**

Each tablet contains:

**Active substance**

Levothyroxine sodium 200 microgram

**3. PHARMACEUTICAL FORM**

Tablet

**4. PACKAGE SIZE**

25 tablets  
50 tablets  
75 tablets  
100 tablets  
125 tablets  
150 tablets  
175 tablets  
200 tablets  
225 tablets  
250 tablets  
30 tablets  
60 tablets  
90 tablets  
120 tablets  
150 tablets  
180 tablets  
210 tablets  
240 tablets  
270 tablets  
300 tablets

**5. TARGET SPECIES**

Dogs and cats.

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Oral use.  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

**9. SPECIAL WARNING(S), IF NECESSARY**

This product may present a risk to humans, particularly children, if ingested. Return unused tablet portion(s) to the open blister.  
Read the package leaflet before use.

**10. EXPIRY DATE**

EXP:

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.  
Keep the blisters in the outer carton in order to protect from light.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only.  
To be supplied only on veterinary prescription.

**14. THE WORDS "KEEP OUT OF SIGHT AND REACH OF CHILDREN"**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Le Vet Beheer B.V.  
Wilgenweg 7  
3421 TV Oudewater  
The Netherlands

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 41821/4031

**17. MANUFACTURER'S BATCH NUMBER**

Lot.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Aluminium-PVC blisters**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Thyroxanil 200 µg tablets  
levothyroxine sodium



**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Le Vet Beheer B.V.

**3. EXPIRY DATE**

EXP:

**4. BATCH NUMBER**

Lot:

**5. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

## **B. PACKAGE LEAFLET**

## **PACKAGE LEAFLET:**

Thyroxanil 200 microgram tablets for dogs and cats

### **1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder

Le Vet Beheer B.V.  
Wilgenweg 7  
3421 TV Oudewater  
The Netherlands

Manufacturer responsible for the batch release:

Lindopharm GmbH  
Neustrasse 82  
D-40721 Hilden  
Germany

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

### **2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Thyroxanil 200 microgram tablets for dogs and cats  
levothyroxine sodium

### **3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS**

Each tablet contains:

**Active substance:**

Levothyroxine sodium	200 microgram
(equivalent to levothyroxine	194 microgram)

White to off white, round and convex tablet with a cross-shaped break line on one side and the number 200 on the other side. The tablets can be divided into halves or quarters.

### **4. INDICATIONS**

Treatment of primary and secondary hypothyroidism.

### **5. CONTRAINDICATIONS**

Do not use in dogs and cats suffering from uncorrected adrenal insufficiency.  
Do not use in cases of known hypersensitivity to levothyroxine sodium or to any of the excipients.



## **6. ADVERSE REACTIONS**

An exacerbation of skin symptoms, with increased pruritus due to shedding of the old epithelial cells, can occur initially. Pruritus and desquamation have been reported very rarely in spontaneous reports.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon. Alternatively you can report via national reporting system {national system details}.

## **7. TARGET SPECIES**

Dogs and cats.

## **8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION**

Oral use.

The recommended starting dose for dogs and cats is 20 µg levothyroxine sodium per kg body weight per day given as a single daily dose or in two equally divided doses. Because of variability in absorption and metabolism, the dosage may require alterations before a complete clinical response is observed. The initial dosage and frequency of administration are merely a starting point. Therapy has to be highly individualised and tailored to the requirements of the individual animal especially for cats and small dogs. See also section "Special precautions for use in animals" for use in animals <2.5 kg. The dose should be adjusted based on clinical response and plasma thyroxine levels. In the dog and cat, absorption of levothyroxine sodium may be affected by the presence of food. The timing of treatment and its relation to feeding should therefore be kept consistent from day to day. To adequately monitor therapy, trough values (just prior to treatment) and peak values (about four hours after dosing) of plasma T4 can be measured. In adequately dosed animals peak plasma concentration of T4 should be in the high-normal range (approximately 30 to 47 nmol/l) and trough values should be above approximately 19 nmol/l. If T4 levels are outside this range the levothyroxine sodium dose can be adjusted in appropriate increments until the patient is clinically euthyroid and serum T4 is within the reference range. The 200 µg tablets enable adjustment of the levothyroxine dose by 50 µg increments per animal and 600 µg tablets enable adjustment of the levothyroxine dose by 150 µg increments per animal. Plasma T4 levels can be retested two weeks after change of dosage, but clinical improvement is an equally important factor in determining individual dosage and this will take four to eight weeks. When the optimum replacement dose has been attained, clinical and biochemical monitoring may be performed every 6 – 12 months.

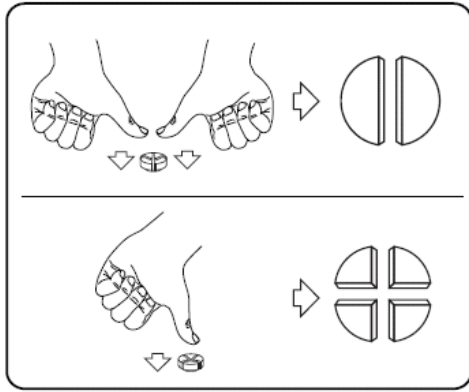
The following table is intended as a guide to dispensing the product at approximately the standard **starting** dose rate of 20 µg levothyroxine sodium per kg bodyweight per day.

Body weight	Administration once daily		Actual dose per kg (µg)	Administration twice daily	
	Thyroxanil 200 µg	Thyroxanil 600 µg		Thyroxanil 200 µg	Thyroxanil 600 µg
>2.5 kg – 5 kg			20 - 10	-	
>5 kg – 7.5 kg			20 - 13.3		
>7.5 kg – 10 kg		or	20 - 15		
>10 kg – 12.5 kg			20 - 16		
>12.5 kg – 15 kg		or	24 - 20		or
>15 kg – 17.5 kg			23.3 - 20		
>17.5 kg – 20 kg			22.9 - 20		
>20 kg – 22.5 kg		or	22.5 - 20		
>22.5 kg – 25 kg			22.2 - 20		
>25 kg – 30 kg		or	24 - 20		or
>30 kg – 40 kg		and	26.7 - 20		
>40 kg – 50 kg		and	25 - 20		
>50 kg – 60 kg			24 - 20		

= ¼      Tablet = ½ Tablet      = ¾ Tablet = 1 Tablet

## 9. ADVICE ON CORRECT ADMINISTRATION

Tablets can be divided into halves or quarters to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



Halves: press down with your thumbs on both sides of the tablet.

Quarters: press down with your thumb in the middle of the tablet.

## 10. WITHDRAWAL PERIOD

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C. Keep the blisters in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of that month.

## 12. SPECIAL WARNINGS

Special warnings for each target species:

The diagnosis of hypothyroidism should be confirmed with appropriate tests.

Special precautions for use in animals:

A sudden increase in demand for oxygen delivery to peripheral tissues, plus the chronotropic effects of levothyroxine sodium, may place undue stress on a poorly functioning heart, causing decompensation and signs of congestive heart failure. Hypothyroid animals with concurrent hypoadrenocorticism have a decreased ability to metabolise levothyroxine sodium and therefore an increased risk of thyrotoxicosis. These animals should be stabilised with glucocorticoid and mineralocorticoid treatment prior to treatment with levothyroxine sodium to avoid precipitating a hypoadrenocortical crisis. After this, thyroid tests should be repeated, then gradual introduction of levothyroxine is recommended (starting with 25% of the normal dose and increasing by 25% increments every fortnight until optimal stabilisation is achieved). Gradual introduction of therapy is also recommended for animals with other concurrent illnesses; particularly in animals with cardiac disease, diabetes mellitus and renal or hepatic dysfunction.

Owing to limitations in size and divisibility of the tablets, it may not be possible to optimally dose animals weighing less than 2.5 kg. Therefore use of the product in these animals should be based on a careful benefit-risk assessment by the responsible veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This product contains a high concentration of levothyroxine sodium and may be harmful when ingested, particularly for children. Pregnant women should handle this veterinary medicinal product with caution. Levothyroxine may cause hypersensitivity (allergy) following ingestion. Avoid skin contact with this product if you know you are sensitized. Wash hands after handling the tablets. In the case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Any unused tablet portion(s) should be returned to the open blister, stored out of the sight and reach of children and always be used at the next administration.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established in pregnant or lactating bitches and queens and therefore use of the product in these animals should be based on a benefit-risk assessment by the responsible veterinarian. However, levothyroxine is an endogenous substance and thyroid hormones are essential for the developing foetus, especially during the first period of gestation. Hypothyroidism during pregnancy may result in major complications such as foetal death and a poor perinatal outcome. Maintenance dose of levothyroxine sodium may need adjustment during pregnancy. Pregnant bitches and queens should therefore be monitored on a regular basis from conception until several weeks after delivery.

Interactions with other medicinal products and other forms of interaction:

A variety of drugs may impair plasma or tissue binding of the thyroid hormones or alter thyroid hormone metabolism (eg. barbiturates, antacids, anabolic steroids, diazepam, furosemide, mitotane, phenylbutazone, phenytoin, propranolol, large doses of salicylates and sulphonamides). When treating animals that are receiving concurrent medication the properties of these drugs should be taken into consideration.

Oestrogens may increase thyroid requirements.

Ketamine may cause tachycardia and hypertension when used in patients receiving thyroid hormones.

The effect of catecholamines and sympathomimetics is increased by levothyroxine.

An increase in the dosage of digitalis may be necessary in a patient that had previously compensated congestive heart failure and that is placed on thyroid hormone supplementation. Following treatment of hypothyroidism in patients with concurrent diabetes, careful monitoring of diabetic control is recommended.

Most patients on chronic high- dose, daily glucocorticoid therapy will have very low or undetectable serum T4 concentrations, as well as subnormal T3 values.

Overdose (symptoms, emergency procedures, antidotes):

Following administration of overdoses thyrotoxicosis could occur. Thyrotoxicosis as a side effect of mild over-supplementation is uncommon in dogs and cats, owing to the ability of these species to catabolise and excrete thyroid hormones. In case of accidental intake of large amounts of the veterinary medicinal product absorption can be decreased by induction of vomiting and oral administration of both activated charcoal and magnesium sulphate once.

In an acute overdose situation in dogs and cats, the clinical signs are extensions of the hormone's physiological effects. Acute overdose of levothyroxine may produce

vomiting, diarrhoea, hyperactivity, hypertension, lethargy, tachycardia, tachypnoea, dyspnoea, and abnormal pupillary light reflexes.

Following chronic over-supplementation in dogs and cats, clinical signs of hyperthyroidism such as polydipsia, polyuria, panting, weight loss without anorexia, and either or both tachycardia and nervousness may theoretically occur. The presence of these signs should result in evaluation of T4 serum concentrations to confirm the diagnosis, and immediate discontinuance of the supplementation. Once the signs have abated (days to weeks), the thyroid dosage has been reviewed, and the animal has fully recovered, a lower dosage may be instituted, with the animal being monitored closely.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS, IF ANY**

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

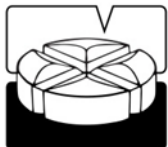
January 2021

**15. OTHER INFORMATION**

Aluminium - PVC blister

Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9 or 10 blisters. 25 or 30 tablets per blister.

Not all pack sizes may be marketed.



Divisible tablet

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved: 03/02/21

