

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TURZINE 16/40 film-coated tablets for cats

2. STATEMENT OF ACTIVE SUBSTANCES

One tablet contains:

Active substances:

Milbemycin oxime	16 mg
Praziquantel	40 mg

Excipients:

Iron oxide (E172)	0.288 mg
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3. PHARMACEUTICAL FORM

Film-coated tablets

4. PACKAGE SIZE

Box with 2 tablets in blister
Box with 4 tablets in blister
Box with 10 tablets in blister
Box with 20 tablets in blister
Box with 50 tablets in blister
Box with 100 tablets in blister

5. TARGET SPECIES

Cats.

6. INDICATION(S)

7. METHOD AND ROUTES OF ADMINISTRATION

Oral administration with or after some food. The dosing is dependant on the bodyweight of the cat.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Keep blister in the outer carton to protect from light.

Half tablets should be returned to the open blister space and inserted back into the cardboard box until the next administration

Do not use after the expiry date stated on the blister and carton after EXP.

In use shelf-life for half tablets is 6 months.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED 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 THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4093

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TURZINE 16/40 film-coated tablets for cats
Milbemycin oxime and praziquantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

**PACKAGE LEAFLET:
TURZINE**

16/40 mg film-coated tablets for cats
4/10 mg film-coated tablets for small cats and kittens

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

Marketing authorisation holder:

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Manufacturer responsible for batch release:

Elanco France
Site Industriel de Huningue
26, Rue de la Chapelle
68332 Huningue Cedex
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

TURZINE 16/40 mg film-coated tablets for cats

TURZINE 4/10 mg film-coated tablets for small cats and kittens

Broad spectrum wormer

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

TURZINE film-coated tablets for cats, small cats, and kittens are available in 2 different sizes:

Name of Tablet (Type of Tablet)	Milbemycin oxime per tablet	Praziquantel per tablet	Excipients q.s. to
TURZINE 4/10 tablets for small cats and kittens (beige to brown, artificial beef flavoured, oblong, divisible)	4 mg	10 mg	132.5 mg
TURZINE 16/40 mg tablets for cats (reddish to reddish brown, artificial beef flavoured, oblong, divisible)	16 mg	40 mg	132.5 mg

4. INDICATIONS

TURZINE is indicated in the cat for treatment of mixed infections by immature and adult cestodes **and** nematodes of the following species:

- Cestodes: *Dipylidium caninum*, *Taenia spp.*, *Echinococcus multilocularis*
- Nematodes: *Ancylostoma tubaeforme*, *Toxocara cati*

The product can also be used in the prevention of heartworm disease (*Dirofilaria immitis*) if concomitant treatment against cestodes is indicated.

5. CONTRAINDICATIONS

Do not use the '**tablets for small cats and kittens**' in cats of less than 6 weeks of age and/or weighing less than 0.5 kg.

Do not use the '**tablets for cats**' in cats weighing less than 2 kg.

6. ADVERSE REACTIONS

In very rare occasions, especially in young cats, systemic signs (such as lethargy), neurological signs (such as ataxia and muscle tremors) and/or gastrointestinal signs (such as emesis and diarrhoea) have been observed after administration of the veterinary medicinal product.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

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).

7. TARGET SPECIES

Cats.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

TURZINE tablets are administered at a minimum recommended dose rate of 2 mg milbemyacin oxime and 5 mg praziquantel per kg body weight.

TURZINE is given by oral administration with or after some food. Doing so ensures optimum protection against heartworm disease.

Depending on the bodyweight of the cat, the practical dosing is as follows:

Weight	TURZINE 4/10 tablets for small cats and kittens	TURZINE 16/40 mg tablets for cats
0.5 – 1 kg	½ tablet (oblong, beige to brown)	
> 1 – 2 kg	1 tablet (oblong, beige to brown)	
> 2 – 4 kg		½ tablet (oblong, reddish to reddish brown)
> 4 – 8 kg		1 tablets (oblong, reddish to reddish brown)
> 8 – 12 kg		1 ½ tablets (oblong, reddish to reddish to reddish brown)

TURZINE can be inserted into a programme for prevention of heartworm disease if at the same time treatment against tapeworms is indicated. TURZINE has a duration of heartworm prevention of one month. For regular prevention of heartworm disease the use of a monosubstance is preferred.

9. ADVICE ON CORRECT ADMINISTRATION

TURZINE is given as a single dose by oral administration with or after some food. Doing so ensures optimum protection against heartworm disease.

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 blister in the outer carton to protect from light.

Half tablets should be returned to the open blister space and inserted back into the cardboard box until the next administration

Do not use after the expiry date stated on the blister and carton after EXP.

In use shelf-life for half tablets is 6 months.

12. SPECIAL WARNINGS

For animal treatment only.

Special precautions for use in animals:

As per good veterinary practice, animals should be weighed to ensure accurate dosing.

No studies have been performed with severely debilitated cats or individuals with seriously compromised kidney or liver function. The product is not recommended for such animals or only according to a benefit/risk assessment by the responsible veterinarian.

User warnings:

Wash hands after use.

In the event of accidental ingestion of the tablets, particularly by a child, seek medical advice and show the doctor the pack and/or the leaflet.

Other precautions

Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (OIE), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

Use during pregnancy and lactation:

The product can be used in breeding animals including pregnant and lactating queens.

Interaction with other medicinal products and other forms of interaction:

The concurrent use of TURZINE with selamectin is well tolerated. No interactions were observed when the recommended dose of the macrocyclic lactone selamectin was administered during treatment with TURZINE at the recommended dose.

Although not recommended, the concomitant use of TURZINE with a spot on containing moxidectin and imidacloprid at recommended dose rates following a single application was well tolerated in one laboratory study in 10 kittens.

The safety and efficacy of the concurrent use have not been investigated in field studies. In the absence of further studies, caution should be taken in the case of concurrent use of the product with any other macrocyclic lactone. Also, no such studies have been performed with reproducing animals.

Overdose (symptoms, emergency procedures, antidotes):

In case of overdose, in addition to signs observed at the recommended dose (see 6), drooling was observed. This sign will usually disappear spontaneously within a day.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2021

15. OTHER INFORMATION

Available pack sizes:

Box with 2 tablets in blister
Box with 4 tablets in blister
Box with 10 tablets in blister
Box with 20 tablets in blister
Box with 50 tablets in blister
Box with 100 tablets in blister

Not all pack sizes may be marketed

For any information about this veterinary medicinal product, please contact Elanco Europe Ltd.

Approved: 12/01/21

