LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TURZINE 2.5/25.0 mg tablets for small dogs and puppies

2. STATEMENT OF ACTIVE SUBSTANCES

One tablet contains:
Active substances:

Milbemycin oxime	2.5 mg
Praziquantel	25.0 mg

3. PHARMACEUTICAL FORM

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

Dogs.

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 dog.
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 30°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.

Half tablets should be stored below 25°C.
Do not use after the expiry date stated on the blister and carton after EXP.
In use shelf-life for half tablets is 1 month.

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 00879/4092

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TURZINE 2.5/25 mg tablets for small dogs and puppies
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

12.5/125 mg tablets for dogs
2.5/25 mg tablets for small dogs and puppies

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 12.5/125 tablets for dogs

TURZINE 2.5/25 mg tablets for small dogs and puppies

Broad spectrum wormer

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

TURZINE tablets for dogs, small dogs, and puppies are available in 2 different sizes:

Name of Tablet (Type of Tablet)	Milbemycin oxime per tablet	Praziquantel per tablet	Excipients q.s. to one tablet of
TURZINE, 2.5/25 mg tablets for small dogs and puppies (white, oblong, divisible)	2.5 mg	25 mg	125 mg
TURZINE, 12.5/125 tablets for dogs (white, round-shaped)	12.5 mg	125 mg	625 mg

4. INDICATIONS

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

- Cestodes: *Dipylidium caninum*, *Taenia spp.*, *Echinococcus spp., Mesocestoides spp*

- Nematodes: *Ancylostoma caninum, Toxocara canis*, *Toxascaris leonina, Trichuris vulpis,*. *Thelazia callipaeda*
  In *Crenosoma vulpis* the product is indicated for a reduction of the level of infection.
  In *Angiostrongylus vasorum,* the product is indicated for a reduction of the level of infection by immature adult (L5) and adult parasite stages (see specific treatment and disease prevention schedules for *A. vasorum* in point "Dosage for each species, route(s) and method of administration").
  Thelazia callipaeda: please refer to specific treatment schedule under section "Dosage for each species, route(s) and method of administration"

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 dogs and puppies'** in dogs of less than 2 weeks of age and/or weighing less than 0.5 kg.
Do not use the '**tablets for dogs'** in dogs weighing less than 5 kg.
Do not use in case of hypersensitivity to the active substances or to any of excipients.

6. ADVERSE REACTIONS

In very rare occasions, systemic signs (such as lethargy), neurological signs (such as muscle tremors and ataxia) and/or gastrointestinal signs (such as emesis, diarrhea, anorexia and drooling) have been observed in dogs 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

Dogs.

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

TURZINE tablets are administered at a minimum recommended dose rate of 0.5 mg milbemycin oxime and 5 mg praziquantel per kg body weight.

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

Weight	TURZINE 2.5/25 mg tablets for small dogs and puppies	TURZINE 12.5/125 mg tablets for dogs
0.5 – 1 kg	½ tablet (oblong, white)	
> 1 - 5 kg	1 tablet (oblong, white)	
> 5 – 10 kg	2 tablets (oblong, white)	1 tablet (round, white)
> 10 – 25 kg		
> 25 – 50 kg		2 tablets (round, white)
> 50 – 75 kg		3 tablets (round, white)

In cases when heartworm disease prevention is used and at the same time treatment against tapeworm is required, TURZINE can replace the monovalent product for the prevention of heartworm disease.

For treatment of *Angiostrongylus vasorum* infections, milbemycin oxime should be given four times at weekly intervals. It is recommended, where concomitant treatment against cestodes is indicated, to treat once with TURZINE and continue with the monovalent product containing milbemycin oxime alone, for the remaining three weekly treatments.

In endemic areas administration of the product every four weeks will prevent angiostrongylosis by reducing immature adult (L5) and adult parasite burden, where concomitant treatment against cestodes is indicated.

For the treatment of *Thelazia callipaeda*, milbemcyin oxime should be given in 2 treatments, seven days apart here concomitant treatment against cestodes is indicated, TURZINE can replace the monovalent product containing milbemycin oxime alone.

9. ADVICE ON CORRECT ADMINISTRATION

TURZINE is given as a single dose by oral administration with or after some food.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 30°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.

Half tablets should be stored below 25°C (only valid for TURZINE 2.5/25 mg tablets for small dogs and puppies).

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

In use shelf-life for half tablets is one month (only valid for TURZINE 2.5/25 mg tablets for small dogs and puppies).

12. SPECIAL WARNINGS

For animal treatment only.

{To be sold on presentation of a veterinary prescription only.}

Studies with milbemycin oxime indicate that the margin of safety in certain dogs of Collie or related breeds is less than in other breeds. In these dogs, the recommended dose should be strictly observed.
The tolerance of TURZINE in young puppies from these breeds has not been investigated.
Clinical signs in Collies are similar to those seen in the general dog population when overdosed (see next).

Overdose (symptoms, emergency procedures, antidotes):

No other signs than those observed at the recommended dose have been observed (see Adverse Reactions).

Special precautions for use in animals:

As per good veterinary practice, animals should be weighed to ensure accurate dosing.
Treatment of dogs with a high number of circulating microfilariae can sometimes lead to the appearance of hypersensitivity reactions, such as pale mucous membranes, vomiting, trembling, laboured breathing or excessive salivation. These reactions are associated with the release of proteins from dead or dying microfilariae and are not a direct toxic effect of the product. The use in dogs suffering from microfilaremia is thus not recommended.

In heartworm risk-areas, or in the case it is known that a dog has been travelling to and from heartworm risk regions, before using TURZINE, a veterinary consultation is advised to exclude the presence of any concurrent infestation of *Dirofilaria immitis*. In the case of a positive diagnosis, adulticidal therapy is indicated before administering TURZINE.

No studies have been performed with severely debilitated dogs 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.

In dogs less than 4 weeks old, tape worm infection is unusual. Treatment of animals less than 4 weeks old with a combination product may therefore not be necessary.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
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 may be used in breeding dogs including pregnant and lactating bitches.

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. In the absence of further studies, caution should be taken in the case of concurrent use of TURZINE and other macrocyclic lactones. Also no such studies have been performed with reproducing animals.

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