PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bayer Praziquantel 50 mg Tablets Praziquantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains 50 mg praziquantel as active substance

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

100 tablets

5. TARGET SPECIES

Cats and dogs.

6. INDICATION(S)

Tapewormer

For the elimination of tapeworms (including *Echinococcus* spp) in cats and dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.

1 tablet per 10 kg.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Do not administer to unweaned kittens and puppies as such animals are rarely infected with tapeworms.

In the interests of good hygiene the person administering the tablets directly to the animal or by adding them to the animal's food should wash their hands afterwards.

10. EXPIRY DATE

Expiry date: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C. Store in a dry place.

Keep the blister in outer carton.

Any part-used tablet should be discarded.

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

For disposal advice please see the package leaflet.

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

For animal treatment only.

AVM-GSL

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

Vetoquinol UK Limited Steadings Barn Pury Hill Business Park Nr. Alderton Towcester Northamptonshire NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4153

17. MANUFACTURER'S BATCH NUMBER

Batch no: {number}

Distributor:

Vetoquinol UK Limited

Steadings Barn

Pury Hill Business Park

Nr. Alderton

Towcester

Northamptonshire

NN127LS

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER FOIL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bayer Praziquantel 50 mg Tablets Praziquantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited logo

3. EXPIRY DATE

Expiry date: {month/year}

4. BATCH NUMBER

Batch no: {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Ad us vet

1 = 10 kg

PARTICULARS TO APPEAR ON THE OUTER PACKAGE			
DISPENSING ENVELOPE			
1. NAME OF THE VETERINARY MEDICINAL PRODUCT			
Bayer Praziquantel 50 mg Tablets Praziquantel			
2. STATEMENT OF ACTIVE SUBSTANCES			
Each tablet contains 50 mg praziquantel as active substance			
3. PHARMACEUTICAL FORM			
Tablet			
4. PACKAGE SIZE			
Tablets supplied			
5. TARGET SPECIES			
For cats and dogs.			
6. INDICATION(S)			
Tapewormer For the elimination of tapeworms (including <i>Echinococcus</i> spp) in cats and dogs.			
7. METHOD AND ROUTE(S) OF ADMINISTRATION			
For oral administration. 1 tablet per 10 kg.			
8. WITHDRAWAL PERIOD			

9. SPECIAL WARNING(S), IF NECESSARY

Do not administer to unweaned kittens and puppies as such animals are rarely infected with tapeworms.

Do not use in dogs weighing less than 2.5 kg.

Do not use in animals known to be allergic to the active substance (praziquantel). In the interests of good hygiene the person administering the tablets directly to the animal or by adding them to the animal's food should wash their hands afterwards.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C. Store in a dry place. Any part-used tablets should be discarded.

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

For further information and disposal advice please see enclosed leaflet.

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

For animal treatment only. AVM-GSL

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

Vetoquinol UK Limited Steadings Barn Pury Hill Business Park Nr. Alderton Towcester Northamptonshire NN12 7LS

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4153

17. MANUFACTURER'S BATCH NUMBER

Distributor: Vetoquinol UK Limited Steadings Barn Pury Hill Business Park Nr. Alderton Towcester Northamptonshire NN12 7LS

Name of pet:
Name of client:
Address:
Date:
Supplied by:

PACKAGE LEAFLET FOR: Bayer Praziquantel 50 mg Tablets

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

Marketing authorisation holder:

Vetoquinol UK Limited Steadings Barn Pury Hill Business Park Nr. Alderton Towcester Northamptonshire NN12 7LS

Manufacturer responsible for batch release:

- KVP Pharma und Veterinär Produkte GmbH, Projensdorfer Str. 324, D-24106 Kiel, Germany
- Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bayer Praziquantel 50 mg Tablets Praziquantel

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each white tablet contains 50 mg praziquantel as active substance.

4. INDICATION(S)

Tapewormer

Tablets for the treatment of tapeworms in cats and dogs.

<u>Uses</u>

For the treatment of adult tapeworms in cats and dogs. The product is effective against both immature and mature forms of adult tapeworms in both cats and dogs.

The product is a highly effective treatment against all the common species of tapeworm infecting cats and dogs in the United Kingdom including *Echinococcus granulosus*, *Taenia ovis, Taenia pisiformis, Taenia multiceps, Taenia hydatigena, Taenia taeniaeformis,* and *Dipylidium caninum*. The product is also effective against *Echinococcus multilocularis* (see section 15).

5. CONTRAINDICATIONS

Do not administer to dogs weighing less than 2.5 kg. Do not administer to unweaned kittens and puppies as such animals are rarely infected with tapeworms.

Do not use in animals known to be allergic to the active substance (praziquantel).

6. ADVERSE REACTIONS

None known.

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

7. TARGET SPECIES

Cats and dogs.

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

5 mg/kg bodyweight (1 tablet per 10 kg body weight).

Dogs	2.5 – 5.0 kg	½ tablet
	6.0– 10.0 kg	1 tablet
	11.0 – 20.0 kg	2 tablets
	21.0 – 30.0 kg	3 tablets
	Over 30 kg	pro rata
Cats	Adult	½ tablet

9. ADVICE ON CORRECT ADMINISTRATION

The product should be given by mouth, preferably by opening the animal's mouth and pushing the tablet over the back of the tongue so that it cannot be rejected. Alternatively, a tablet can be wrapped in a piece of meat or butter and offered to the animal or crushed and mixed with the food.

A single dose is all that is required. However, for dogs in rural areas and for packs of hounds, this dose should be repeated every four weeks to ensure that newly acquired tapeworms are destroyed before reaching maturity. Dosing must be associated with strict control of the dog's diet to ensure that uncooked offal is not eaten.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not store above 25°C. Store in a dry place.

Keep the blister in outer carton.

Any part-used tablets should be discarded.

Do not use after the expiry date stated on the outer carton after EXP:. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

FOR ANIMAL TREATMENT ONLY.

In the interests of good hygiene, persons administering the tablets directly to an animal or adding them to the animal's food should wash their hands afterwards.

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

Dispose of any empty packaging and any remaining product in the household refuse.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2022

15. OTHER INFORMATION

Fleas serve as intermediate hosts for one common type of tapeworm – Dipylidium caninum. To avoid reinfection with this parasite, flea control of the animal and its housing should be carried out at the same time. Unless flea control is complete, an infected flea population may survive and retreatment of the animal may be necessary.

Since it contains praziquantel, the product is effective against *Echinococcus* multilocularis, which does not occur in the UK but is becoming more common in some European countries. As a precautionary measure to prevent establishment of E multilocularis in the UK it is recommended that all cats and dogs entering the country be treated with praziquantel.

Vm 08007/4153

AVM-GSL

Pack size: Carton of 24, 48, 100 or 104 tablets.

Distributor:

Vetoquinol UK Limited Steadings Barn Pury Hill Business Park

Nr. Alderton **Towcester** Northamptonshire **NN127LS**

Approved: 04 August 2022