

ANNEX III
LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

WORMclear Praziquantel 20 mg Spot-on Solution for Cats
Praziquantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each tube contains 0.5 ml of solution equivalent to 20 mg praziquantel/tube.

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

2 tubes x 0.5 ml
4 tubes x 0.5 ml
20 mg solution

5. TARGET SPECIES

Cats

6. INDICATION(S)

For the treatment of tapeworms of cats. The product is effective against mature and immature forms of *Dipylidium caninum*, *Taenia* species and *Echinococcus multilocularis*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The minimum dose rate is 8 mg/kg bodyweight equivalent to 1 tube per 2.5 kg.

Bodyweight (kg)	Tubes
1 – 2.5 kg	1
MORE THAN 2.5 – 5 kg	2
MORE THAN 5 kg	3

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

ALWAYS READ THE PACKAGE LEAFLET CAREFULLY BEFORE USE. FOR EXTERNAL USE ONLY.

Do not administer by mouth.

Do not use this product on cats weighing less than 1.0 kg.

Do not allow recently treated animals to groom each other.

There are no contraindications against use during pregnancy and lactation.

Do not use if your cat is sick or recovering from an illness.

Do not use if your cat is allergic to any of the ingredients.

If signs of disease persist or appear, consult a veterinary surgeon.

User safety

The product can be irritant to the skin and eyes.

Care should be taken to prevent contact of the solution with the skin or eyes.

If contact with the skin occurs, wash off any skin contamination with soap and water immediately.

If accidental contact occurs with the eyes, flush the affected eyes thoroughly with clean fresh water.

In the event of skin or eye contact, seek medical advice if irritation persists and show the doctor this package.

Do not stroke or groom animals until the area of application is dry (typically around 1 hour after application)

Wash hands thoroughly after use.

Do not eat, drink or smoke during application.

10. EXPIRY DATE

Expiry date: {month/year}

Do not use after the expiry date.

11. SPECIAL STORAGE CONDITIONS

Store away from food, drink and animal feedingstuffs.

Keep tubes in outer carton.

The solvent in the product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

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

After use, replace cap on tube. Dispose of empty packaging and any remaining product in the household refuse

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 08007/4175

17. MANUFACTURER’S BATCH NUMBER

Batch No.: {number}

Distributed by:

Call our Helpline on 0333 0066236, email us at info@uk.beaphar.com or write to us at Beaphar UK Ltd, Rook Tree Farm, Withersfield Road, Great Wratting, Suffolk, CB9 7HD.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

TUBE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

WORMclear Praziquantel 20 mg Spot-on

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

20 mg

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

0.5 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

BN: {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

For external use only.

Vm 08007/4175

AVM-GSL

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

WORMclear Praziquantel 20 mg Spot-on Solution for Cats

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited

3. EXPIRY DATE

Expiry date: {month/year}

4. BATCH NUMBER

BN: {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

For external use only.

1 x 0.5 ml tube

Read carton text and package leaflet before using the product.

Vm 08007/4175

AVM-GSL

B. PACKAGE LEAFLET

**PACKAGE LEAFLET FOR:
WORMclear Praziquantel 20 mg Spot-on Solution for 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:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

WORMclear Praziquantel 20 mg Spot-on Solution for Cats
Praziquantel

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

The active ingredient is praziquantel which kills your pet's tapeworms. Each tube of product contains 0.5 ml of liquid containing 20 mg of praziquantel. The solution also contains inactive ingredients which are needed to allow the drug to be absorbed across the skin and into the cat's body where it can be effective.

Clear, colourless to slightly reddish liquid.

4. INDICATION(S)

The product is used for the treatment of tapeworms. It is effective against adult and immature forms of tapeworms known as *Dipylidium caninum* and tapeworms of the *Taenia* species. The product has been specifically designed for administration to cats.

5. CONTRAINDICATIONS

Do not use this product on animals weighing less than 1 kg.

6. ADVERSE REACTIONS

Animal safety

The product is bitter tasting and salivation may occasionally occur if the cat licks the application site immediately after treatment. This is not a sign of poisoning and disappears within a few minutes without treatment.

Occasionally a local reaction, such as scurf or mild exudation may be observed at the application site. The reaction is usually mild and will resolve in a short period of time without any further treatment.

Do not allow recently treated animals to groom each other.

7. TARGET SPECIES

Cats.

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

The product should be administered at monthly intervals or when signs of tapeworm infestation appear. The number of tubes to be used on your cat depends on how much it weighs.

For cats weighing from 1 to 2.5 kg: use 1 tube.

For cats weighing over 2.5 kg up to 5 kg: use 2 tubes.

For cats weighing more than 5 kg: use 3 tubes.

9. ADVICE ON CORRECT ADMINISTRATION

Warning: Do NOT administer the product by mouth.

Weigh your cat to see how many tubes of the product will be required.

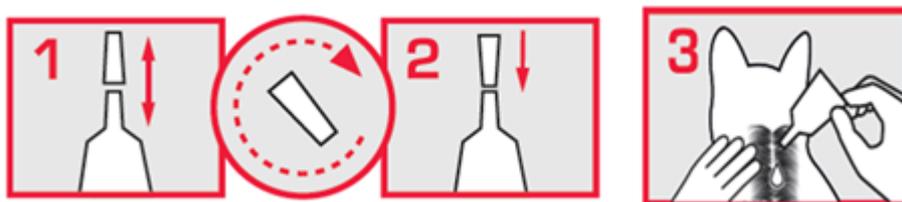
Take the required number of tubes from the blister pack.

Hold one tube in an upright position with the cap at the top.

Twist and pull off the cap.

Reverse the cap and replace it onto the tube.

Twist reversed cap, this will break the seal across the top of the tube.



On the back of the animal's neck, immediately behind the head, part the coat until the skin is visible.

Place the tip of the opened tube on the skin and squeeze tube firmly several times to empty the entire contents directly onto the skin. When it is necessary to use more than one tube, care must be taken to prevent the solution running off the skin of the animal. In this situation it is advised that the applications should be made slowly to allow time for absorption of the solution. Only begin application from the second or third tubes when the contents of the previous tube have been completely absorbed.

It is particularly important to apply the dose to an area where it cannot be licked off. Application to the back of the neck at the base of the skull will minimise the opportunity for the cat to lick the product.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store this product away from food, drink and animal feedingstuffs.

Do not administer this product to your pet after the expiry date on the carton. The expiry date refers to the last day of that month.

The solvent in the product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

12. SPECIAL WARNING(S)

For external use only.

Care should be taken to avoid the contents of the tube coming into contact with the eyes or mouth of the recipient animal.

If signs of disease persist or appear, consult a veterinary surgeon.

User safety – IMPORTANT: ALWAYS READ THIS SECTION CAREFULLY

This product can be irritant to the skin and eyes.

Care should be taken to prevent contact of the solution with the skin or eyes.

If contact with the skin occurs, wash off any skin contamination with soap and water immediately.

If accidental contact occurs with the eyes, flush the affected eyes thoroughly with clean fresh water.

In the event of skin or eye contact, seek medical advice if irritation persists and show the doctor this package.

Do not stroke or groom animals until area of application is dry (typically around 1 hour after application).

Wash hands thoroughly after use.

Do not eat, drink or smoke during application.

Store away from food, drink or animal feedingstuffs.

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

After you have applied the product replace the cap on the tube. Dispose of empty packaging and any remaining product in the household refuse.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2020

15. OTHER INFORMATION

Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas and mice is undertaken. Flea infestations can be controlled by the regular use of effective flea control remedies.

Mice control: if cats roam and hunt, they will come into contact with, and possibly consume, mice. As the mouse is one of the hosts of a tapeworm known as *Taenia taeniaformis*, re-infestation of the cat with this tapeworm is impossible to prevent.

For animal treatment only.

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Pack size: Carton with 2 or 4 tubes.

To safeguard the health of yourself and your pet, please keep this leaflet and read it before you apply the product to your pet. It provides a summary of information about this veterinary medicine. For any information about this veterinary medicinal product, please contact the local distributor.

Distributed by:
Beaphar UK Limited
Rook Tree Farm
Withersfield Road
Great Wratting
Suffolk
CB9 7HD
Tel: 0333 0066236
Email: info@uk.beaphar.com

Approved 05 November 2020



A. Hunter.