

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Droncit SPOT-ON 20 mg solution.
Tapewormer

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

This pack comprises 4 tubes, each containing 0.5 ml of solution equivalent to 20 mg praziquantel/tube.

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

4 tubes x 0.5 ml 20 mg solution.

5. TARGET SPECIES

Cats.

6. INDICATION(S)

IMPORTANT: USE CORRECTLY TO SAFEGUARD YOUR PET AND YOUR HEALTH. ALWAYS READ THE PACKAGE LEAFLET CAREFULLY BEFORE USE.

Use: For the treatment of tapeworms of cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

1. Do NOT administer Droncit Spot-on by mouth.
2. Do not use this product on cats weighing less than 1 kg.
3. Do not allow recently treated animals to groom each other.
4. If signs of disease persist or appear, consult a veterinary surgeon.

User Safety

1. The product can be irritant to the skin and eyes.

2. Care should be taken to prevent contact of the solution with the skin or eyes.
3. If contact with the skin occurs, wash off any skin contamination with soap and water immediately.
4. If accidental contact occurs with the eyes, flush the affected eyes thoroughly with clean fresh water.
5. In the event of skin or eye contact, seek medical advice if irritation persists and show the doctor this package.
6. Do not stroke or groom animals until area of application is dry (typically around 1 hour after application).
7. Wash hands thoroughly after use.
8. Do not eat, drink or smoke during application.
9. Store away from food, drink or animal feeding stuffs.

FOR EXTERNAL USE ONLY.

10. EXPIRY DATE

Expiry date: {month/year}

11. SPECIAL STORAGE CONDITIONS

Store away from food, drink or animal feeding stuffs. Do not use after expiry date. After use replace cap on tube. The solvent in Droncit Spot-on may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials. Keep tubes in outer carton.

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

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

[Distribution category]

AVM-GSL

FOR ANIMAL TREATMENT ONLY.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight 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 08007/4157

17. MANUFACTURER'S BATCH NUMBER

Batch No.: {number}

Manufactured by: KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str.
324, D-24106 Kiel, Germany

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS : UNIT DOSE TUBE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Droncit SPOT-ON

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contains 20 mg praziquantel in 0.5 ml.

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.

AVM-GSL

For external use only
Vm 08007/4157
Vetoquinol UK Limited logo

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
BLISTER FOIL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Droncit SPOT-ON 20 mg Solution

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited logo

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.

Contains 20 mg praziquantel in 0.5 ml.

1 x 0.5 ml tube

Read Carton text and Package Leaflet before using the product.

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

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR: DRONCIT SPOT-ON 20 mg SOLUTION

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

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

Manufacturer: KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324, 24106 Kiel, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Droncit SPOT-ON 20 mg solution
Tapewormer

For the treatment of tapeworms of cats. To safeguard the health of yourself and your pet, please keep this leaflet and read it before you apply the product to your pet.

Please read this leaflet carefully before you apply the product to your pet. It provides a summary of information about this veterinary medicinal product. Please ask your veterinary surgeon if you have any questions. This leaflet applies only to Droncit Spot-on.

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

What is Droncit-Spot-on?

This product is called Droncit Spot-on and each pack comprises 4 plastic tubes. 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.

4. INDICATION(S)

What is Droncit Spot-on used for?

Droncit Spot-on is used for the treatment of tapeworms. It is effective against adult and immature forms of the tapeworms known as *Dipylidium caninum* and tapeworms of the *Taenia* species. The product has been specifically designed for administration to cats. Droncit Spot-on must only be used in cats weighing more than 1 kg bodyweight.

5. CONTRAINDICATIONS

Do not allow recently treated animals to groom each other.
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 following treatment. This reaction is mild and will resolve in a short period of time without any further treatment.

7. TARGET SPECIES

Cats.

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

When to administer Droncit Spot-on?

Droncit Spot-on 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 of Droncit Spot-on.

For cats weighing over 2.5 kg up to 5 kg use 2 tubes of Droncit Spot-on.

For cats weighing more than 5 kg: use 3 tubes of Droncit Spot-on.

9. ADVICE ON CORRECT ADMINISTRATION

How to administer Droncit Spot-on?

Warning: Do NOT Administer Droncit Spot-on by Mouth.

Weigh your cat to see how many tubes of Droncit Spot-on he/she will require. 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 tube when the contents of the previous tube has 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(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children. Store this product away from food, drink and animal feeding stuffs. After you have applied the product, replace the cap on the tube. Dispose of empty packaging and any remaining product in the household refuse. The solvent in Droncit Spot-on may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials. Do not administer this product to your pet after the expiry date on the carton.

12. SPECIAL WARNING(S)

After application of Droncit Spot-on

User safety – IMPORTANT: ALWAYS READ THIS SECTION CAREFULLY

1. This product can be irritant to the skin and eyes.
2. Care should be taken to prevent contact of the solution with the skin or eyes.
3. If contact with the skin occurs, wash off any skin contamination with soap and water immediately.
4. If accidental contact occurs with the eyes, flush the affect eyes thoroughly with clean fresh water.

5. In the event of skin or eye contact, seek medical advice if irritation persists and show the doctor this package.
 6. Do not stroke or groom animals until area of application is dry (typically around 1 hour after application).
 7. Wash hand thoroughly after use.
 8. Do not eat, drink or smoke during application.
 9. Store this product away from food, drink or animal feeding stuffs.
- If signs of disease persist or appear, consult a veterinary surgeon.

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

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

Further information

Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. 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 taeniaeformis* re-infestation of the cat with this tapeworm will be impossible to prevent.

For animal treatment only.

AVM-GSL

Marketing Authorisation

The Marketing Authorisation number is Vm 08007/4157

Approved 05 November 2020

