ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quantex 20 mg Spot-on Solution
Praziquantel

2. STATEMENT OF ACTIVE SUBSTANCES

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

Excipients
N-methylpyrrolidone 497.8 mg

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)

Tapewormer.
For the treatment of tapeworms of cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

IMPORTANT: USE CORRECTLY TO SAFEGUARD YOUR PET AND YOUR HEALTH.

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

Do NOT administer Quantex 20 mg Spot-on Solution 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.

Use during pregnancy and lactation – read the package leaflet.
The safety of the veterinary medicinal product has not been established in cats during pregnancy, lactation or in animals intended for breeding.

User safety

For full user safety warnings, read the package leaflet.
Pregnant women and women suspected of being pregnant should not administer the product.
Do not stroke or groom animals until the area of application is dry (typically around 1 hour after application)
Wash hands thoroughly after use.

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 feeding stuffs.
Keep the container and the leaflet in the outer carton.The solvent in Quantex 20 mg Spot-on Solution may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

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

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

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

[Distribution category]

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 08007/4172

17. MANUFACTURER'S BATCH NUMBER

Batch no. {number}

LOCAL REPRESENTATIVE:
MiGroup CVS House,
Owen Road, Diss,
Norfolk IP22 4ER,
United Kingdom
Tel: 01379 658042
products@cvsvets.com

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

TUBE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quantex 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.
For external use only
Vm 08007/4172

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MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER FOIL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quantex 20 mg Spot-on Solution
Contains 20 mg praziquantel in 0.5 ml.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited

3. EXPIRY DATE

EXP: {month/year}

4. BATCH NUMBER

Batch no.: {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 08007/4172

AVM-GSL

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR: QUANTEX 20 mg SPOT-ON SOLUTION

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

Quantex 20 mg Spot-on Solution
Praziquantel

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

This product is called Quantex 20 mg Spot-on Solution 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. Each tube contains 497.8 mg of N-methylpyrrolidone.

Clear, colourless to slightly reddish liquid.

4. INDICATION(S)

Tapewormer
For the treatment of tapeworms of cats.
Quantex 20 mg Spot-on Solution 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. Quantex 20 mg Spot-on Solution must only be used in cats weighing more than 1 kg bodyweight.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use this product on animals weighing less than 1 kg.

6. ADVERSE EVENTS

Cats and kittens
Animal safety

Occasionally a transient local reaction, such as scurf, mild exudation, hair loss, sore, reddening and itching may be observed at the application site following treatment. The reaction is usually mild and will resolve in a short period of time without any further treatment. If you have any concerns please talk to your veterinary surgeon.

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.

7. TARGET SPECIES

Cats

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

Quantex 20 mg Spot-on Solution 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.

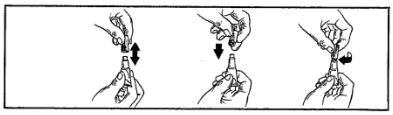
For cats weighing from 1 to 2.5 kg: use 1 tube of Quantex 20 mg Spot-on Solution.
For cats weighing over 2.5 kg up to 5 kg: use 2 tubes of Quantex 20 mg Spot-on Solution.
For cats weighing more than 5 kg: use 3 tubes of Quantex 20 mg Spot-on Solution.

9. ADVICE ON CORRECT ADMINISTRATION

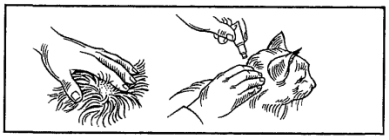
Warning: Do NOT administer Quantex 20 mg Spot-on Solution by mouth.

Weigh your cat to see how many tubes of Quantex Spot-on will be required. Underdosing could result in ineffective use and may favour resistance development.

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.

Do not allow recently treated animals to groom each other.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store this product away from food, drink and animal feeding stuffs.
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 Quantex 20 mg Spot-on Solution 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.

The safety of the veterinary medicinal product has not been established in cats during pregnancy, lactation or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

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

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.
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 leaflet.
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.

For Animal Treatment Only

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.

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. Medicines should not be disposed of via wastewater. These measures should help to protect the environment.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

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 taeniaeformis,* re-infestation of the cat with this tapeworm is impossible to prevent.

AVM-GSL

Vm 08007/4172
Pack size: Carton with 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.

Please read this leaflet carefully before you apply the product to your pet. It provides a summary of information about this veterinary medicine. Please ask your veterinary surgeon if you have any questions. This leaflet applies only to Quantex 20 mg Spot-on Solution.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Gavin Hall

Approved: 21 January 2025