PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RidaWorm 20 mg Spot-on Solution for Cats and Kittens
Praziquantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.5 ml pipette contains:
Praziquantel 20 mg

3. PHARMACEUTICAL FORM

Spot-on Solution

4. PACKAGE SIZE

1 x 0.5 ml
2 x 0.5 ml
3 x 0.5 ml
4 x 0.5 ml
6 x 0.5 ml

5. TARGET SPECIES

Cats

6. INDICATION(S)

RidaWorm 20 mg Spot-on Solution for Cats and Kittens treats tapeworms.
RidaWorm is effective against mature and immature forms of:
Dipylidium caninum
Taenia spp
Echinococcus multilocularis

Please note that this product is only effect against tapeworms and does not treat other parastitic worms, including roundworms.
Kills tapeworms

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For topical administration.
Read the package leaflet before use.
Dose: 1 pipette per 2.5Kg bodyweight
Weigh cat/kitten before use.

Cat's weight	No. of pipettes
1 – 2.5 kg	1 Pipette
>2.5 – 5 kg	2 Pipette
>5 – 7.5 kg	3 Pipette

It is recommended to re-apply the product when signs of tapeworm infestation re-appear or at monthly intervals.

	1st Treatment Date:	2nd Treatment Due:	3rd Treatment Due:	4th Treatment Due:
Date				

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Please read the package leaflet before use for full instructions, including user warnings.
Do not use in cats weighing less than 1 kg.
The product can be irritating to the skin and eyes.
Care should be taken to avoid the contents of the tube coming into contact with the skin, eyes and mouth, including hand-to-mouth and hand-to-eye contact.
If accidental contact with the skin or eyes occurs, wash off any skin contamination with soap and water immediately. Rinse 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 eat, drink or smoke during application.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.
Laboratory studies with the excipient N-methyl-2-pyrrolidone in rabbits and rats have shown evidence of teratogenic, foetotoxic, maternotoxic and reprotoxic effects. Avoid direct contact with the product and application site.
Do not stroke or groom animals until the area of application is dry (at least one hour after application).
Wash hands thoroughly after use.
Keep product in the outer carton until ready to use.
Store away from food, drink and animal feeding stuffs.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of waste material in accordance with local requirements.

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 sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/4046

17. MANUFACTURER'S BATCH NUMBER

BN {number}

Text in italics will be overprinted at production stage

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Label for 0.5 ml pipette}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RidaWorm 20mg Spot-on Solution for Cats and Kittens
Praziquantel

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Praziquantel 20 mg

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

0.5 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on

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

Text in italics will be overprinted at production stage

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
{Sachet Text}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RidaWorm 20mg Spot-on Solution for Cats and Kittens
Praziquantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

BN {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For Animal Treatment Only

Note: Text in italics will be printed at production

PACKAGE LEAFLET FOR:

RidaWorm 20mg Spot-on Solution for Cats and Kittens

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

Chanelle Pharmaceuticals Manufacturing Ltd, Loughrea, Co. Galway, Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

RidaWorm 20 mg Spot-on Solution for Cats and Kittens
Praziquantel

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

Each 0.5 ml pipette contains:

Praziquantel	20 mg
Butylhydroxytoluene (E321)	0.5 mg

Spot-on Solution
Clear, colourless to pale amber solution

4. INDICATION(S)

For the treatment of tapeworms in cats. The product is effective against mature and immature forms of *Dipylidium caninum* and *Taenia* species. The product is also effective against *Echinococcus multilocularis*.
Please note that this product is only effective against tapeworms and does not treat other parasitic worms, including roundworms.

5. CONTRAINDICATIONS

Do not use on cats weighing less than 1 kg.
Do not use in cases of hypersensivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

On very rare occasions a transient local reaction such as scurf (flaking skin) or mild exudation (weeping) may be observed at the application site following treatment.
On very rare occasions salivation may occur if the cat licks the application site immediately after treatment, as the product is bitter tasting. This is not a sign of intoxication and disappears after a short time without treatment.

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).

If you notice any side effects, even those not already listed in this package leaflet or if you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats

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

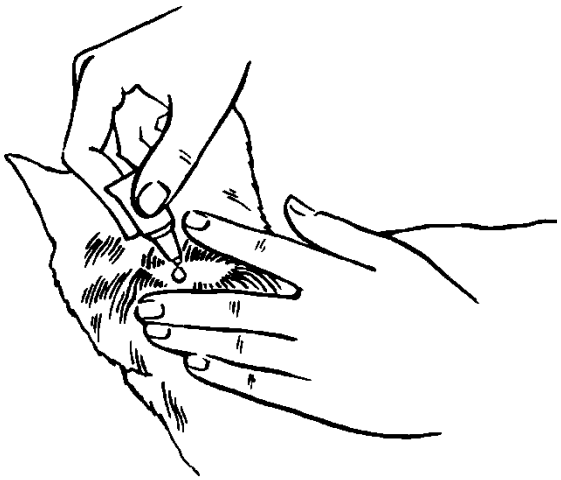
Route of administration and dosage:
External use only.
Administer by topical application to the skin as follows:
The minimum dose rate is 8 mg/kg bodyweight, which equates to 1 pipette per 2.5 kg bodyweight.

Bodyweight	Number of Pipettes	Quantity of Praziquantel	mg/kg bw
1 – 2.5 kg	1	20 mg	8 – 20
>2.5 – 5 kg	2	40 mg	8 – 16
>5 kg	3	60 mg	Maximum 12

Method of Administration

Remove one pipette from the package. Hold pipette in an upright position. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette. Twist and pull the snap-off top of the pipette to enable the contents to be expelled.

Part the hair on the cat's neck at the base of the skull until the skin is visible.



Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly on to the skin. Application at the base of the skull will minimise the opportunity for the cat to lick the product.
To minimise the possibility of run-off after application of more than one pipette, it is advised that the applications should be performed slowly to allow absorption and that it may be advisable to allow the contents of the previous pipette to be absorbed before applying another.

Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken.

Flea control: flea infestations can be controlled by the regular use of effective flea control remedies.

Mice control: if cats roam and hunt, contact with, and consumption of, mice and subsequent re-infestation with *Taenia taeniaeformis* is impossible to prevent.

It is recommended to re-apply the product when signs of tapeworm infestation re-appear or at monthly intervals.

9. ADVICE ON CORRECT ADMINISTRATION

Application of the solution as directed minimises the possibility that the animal will lick the solution off.

10. WITHDRAWAL PERIOD(S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Store in a dry place in the original package.
Do not use this veterinary medicinal product after the expiry date stated on the label. The expiry date refers to the last day of the month.
Store away from food, drink and animal feeding stuffs.
Keep out of the sight and reach of children.
Do not remove the pipette from the sachet until ready for use.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Care should be taken to avoid the contents of the pipette coming into contact with the eyes or mouth of the recipient animal.
For external use only.
Do not allow recently treated animals to groom each other.

Special precautions to be taken by the person administering the medicinal product to animals:
The product can be irritating to the skin and eyes.
Care should be taken to avoid the contents of the tube coming into contact with the skin, eyes and mouth, including hand-to-mouth and hand-to-eye contact.
If accidental contact with the skin or eyes occurs, wash off any skin contamination with soap and water immediately. Rinse 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 eat, drink or smoke during application.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.
Laboratory studies with the excipient N-methyl-2-pyrrolidone in rabbits and rats have shown evidence of teratogenic, foetotoxic, maternotoxic and reprotoxic effects. Avoid direct contact with the product and application site.

Do not stroke or groom animals until the area of application is dry (at least one hour after application).
Wash hands thoroughly after use.
Keep product in the outer carton until ready to use.
Store away from food, drink and animal feeding stuffs.

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 (e. g. experts or institutes of parasitology). If the cat has visited areas where *Echinococcus* spp. are prevalent, a veterinarian should be consulted.
Keep recently treated pets away from varnished, polished, plastic or leather surfaces.

Use during pregnancy and lactation:
There are no contraindications against use during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
No incompatibility has been observed between this product at the recommended dose and a range of common veterinary treatments.

Overdose:
Overdosing can lead to slight skin reactions which disappear without treatment within a few days.

Incompatibilities:
None known

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

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

June 2020

15. OTHER INFORMATION

Carton containing 1, 2, 3, 4 or 6 pipettes in individual foil sachets.
Not all pack sizes may be marketed.
For animal treatment only
Vm 08749/4046

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Approved 10 June 2020