1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ridaworm 20mg Spot-on Solution for small cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml pipette contains:

Active substance:
Praziquantel 20 mg

Excipient(s):
Butylhydroxytoluene (E321) 0.5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
Clear colourless to pale amber solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

For the treatment of infections by tapeworms of cats weighing up to 2.5 kg: The product is effective against mature and immature stages of *Dipylidium caninum* and *Taenia (Hydatigera) taeniaeformis*

4.3 Contraindications

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

4.4 Special warnings for each target species

Do not allow recently treated animals to groom each other.
When applying the veterinary medicinal product, special attention should be paid in long hair breeds in order to ensure that it is applied directly to the skin and not on the hair, as this could lead to a lower bioavailability of the active substance and thus, to a reduced activity.

Shampooing and immersion of the animals in water directly after treatment may reduce the efficacy of the product. Treated animals therefore should not be bathed until the solution has dried.

It is recommended to treat all the animals living in the same household concomitantly.

When infection with tapeworms has been confirmed, concomitant treatment against intermediate hosts, such as fleas and lice, should be discussed with a veterinarian to prevent re-infection.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. The use of this product should take into account local epidemiological information about susceptibility of the target helminths.

4.5 Special precautions for use

i) Special precautions for use in animals

Apply only to the skin surface and on intact skin.
It is important to apply the veterinary medicinal product to a skin area where the cat cannot lick it off: on the neck or between shoulders.
Avoid the treated cats or other animals in the household licking the site of application while it is wet.
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.
For severely debilitated or heavily infested cats, use only according to a benefit/risk assessment by the responsible veterinarian.

ii) 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 pipette coming into contact with the skin, eyes or 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.
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. Pregnant women, women intending to conceive and breastfeeding women should not administer the product.
Do not stroke or groom animals until area of application is dry (at least one hour after application).
Wash hands thoroughly after use.
Do not eat, drink or smoke during application.
Keep the product in the outer carton until ready to use.
Store away from food, drink and animal feeding stuffs.

<u>Other precautions</u>
The solvent in the veterinary medicinal product may damage various materials such as plastics, leather or fabrics. Avoid contact of the product or the wet application area (s) with such materials.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases a transient local reaction such as scurf or mild exudation may be observed at the application site following treatment.

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 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).

4.7 Use during pregnancy, lactation or lay

Laboratory studies with praziquantel in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. The safety of praziquantel was established in pregnant and lactating queens. However laboratory studies with the excipient N-methyl-2pyrrolidone in rabbits and rats have shown evidence of teratogenic, foetotoxic, maternotoxic and reprotoxic effects, therefore use of the product is not recommended during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

Spot-on use. Animals should be weighed accurately prior to treatment.

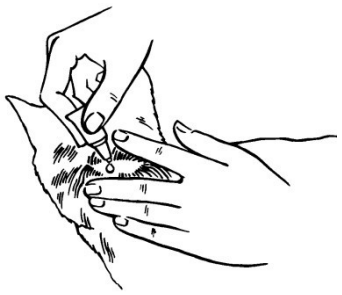
Dosage and Treatment Schedule

The minimum dose rate is 8 mg/kg bodyweight, which equates to 1 pipette of 0.5 ml for a small cat (1 to 2.5 kg) corresponding to a dose rate of 8-20 mg/kg bw.

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. Snap back the tip 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 onto the skin. Application at the base of the skull will minimise the opportunity for the cat to lick the product.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, Quinolone derivatives and related substances ATCvet code: QP52AA01

5.1 Pharmacodynamics

Praziquantel is active against all stages of development of intestinal tapeworms. The spectrum of action of praziquantel includes all important cestodes species of the cat including *Taenia (Hydatigera) taeniaeformis* and *Dipylidium caninum.* Praziquantel works against all intestinal stages of these parasites found in cats.
Praziquantel is absorbed by the parasites very quickly over their surface and evenly distributed in the parasite. In vitro and in vivo, very rapid damage to the parasite integument and subsequent contraction and paralysis of the parasites occur. The basis for the rapid onset of action is in particular the praziquantel-induced change in the permeability of the parasite membranes for Ca ++, which leads to a dysregulation of the parasite metabolism and to its death.

5.2 Pharmacokinetics

Praziquantel is quickly absorbed through the skin after dermal application of the recommended dose of 8 mg / kg body weight of cats. Maximum serum concentrations are reached after approx. 3 hours at approx. 0.06 mg / l. As studies in various animal species show, praziquantel is rapidly metabolized in the liver. The main metabolites of praziquantel are monohydroxyhexyl derivatives. Excretion is predominantly via the kidneys

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene E321
N-methylpyrrolidone

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Store in the original package in order to protect from light.

6.5 Nature and composition of immediate packaging

A white pipette composed of a heat-formed shell composed of polypropylene/cyclic olefin copolymer/ethylene vinyl alcohol/polypropylene layer.

Carton containing 1, 2, 3, 4 or 6 pipettes in individual foil sachets.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION

10. DATE OF REVISION OF THE TEXT

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ridaworm 20 mg Spot-on Solution for small cats
Praziquantel

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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)

For the treatment of infections by tapeworms of cats weighing up to 2.5 kg: The product is effective against mature and immature stages of *Dipylidium caninum* and *Taenia (Hydatigera) taeniaeformis*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For topical administration.
Read the package leaflet before use.
Dose: The minimum dose rate is 8 mg/kg bodyweight.
Weigh cat before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from light

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

Read the package leaflet before use.

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

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the 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)

17. MANUFACTURER'S BATCH NUMBER

BN{number}

PARTICULARS TO APPEAR ON THE SMALL IMMEDIATE PACKAGE UNIT

Label for 0.5 ml pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ridaworm 20 mg Spot-on Solution for small cats
Praziquantel

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Praziquantel 20 mg

3. PACKAGE SIZE

0.5 ml

4. ROUTE OF ADMINISTRATION

Spot-on

5. EXPIRY DATE

EXP {month/year}

6. MANUFACTURER'S BATCH NUMBER

BN{number}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Note: Text in italics will be printed at production

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SACHET TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ridaworm 20 mg Spot-on Solution for small cats
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(S)

6. BATCH NUMBER

BN {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Note: Text in italics will be printed at production

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B. PACKAGE LEAFLET

PACKAGE LEAFLET

Ridaworm 20 mg Spot-on Solution for small 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 and Manufacturer responsible for batch release
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea, Co.
Galway,
Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ridaworm 20 mg Spot-on Solution for small cats
Praziquantel

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

Each pipette contains:

Praziquantel	20 mg
Butylhydroxytoluene E321	0.5 mg

Clear colourless to pale amber solution.

4. INDICATION(S)

For the treatment of infections by tapeworms of cats weighing up to 2.5 kg: The product is effective against mature and immature stages of *Dipylidium caninum* and *Taenia (Hydatigera) taeniaeformis*

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

In very rare cases a transient local reaction such as scurf or mild exudation may be observed at the application site following treatment.

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 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 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

Spot-on use. Animals should be weighed accurately prior to treatment.

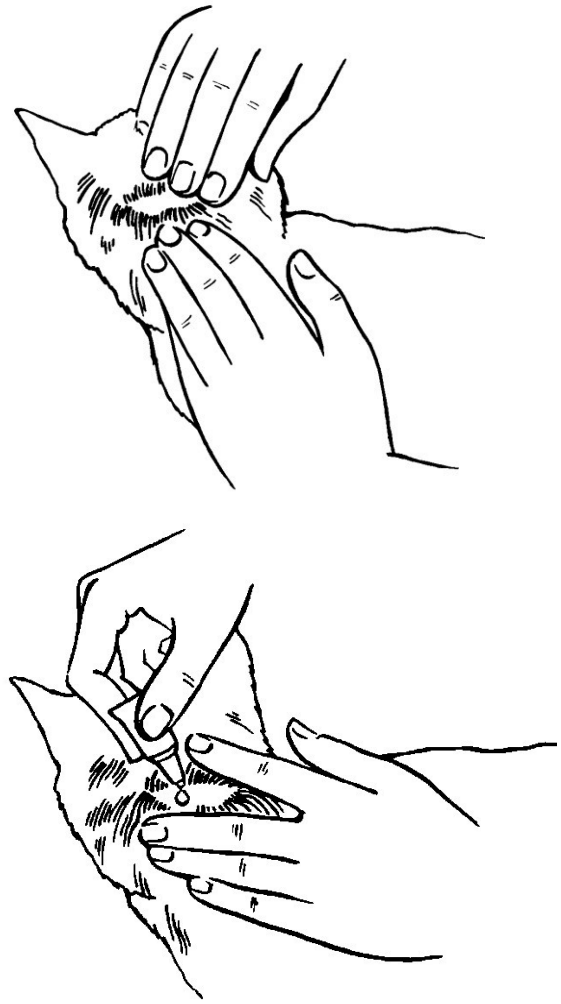
Dosage and Treatment Schedule

The minimum dose rate is 8 mg/kg bodyweight, which equates to 1 pipette of 0.5 ml for a small cat (1 to 2.5 kg) corresponding to a dose rate of 8-20 mg/kg bw.

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. Snap back the tip 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 onto the skin. Application at the base of the skull will minimise the opportunity for the cat to lick the product.

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

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in the original package in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after {exp}. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species
Do not allow recently treated animals to groom each other.
When applying the veterinary medicinal product, special attention should be paid in long hair breeds in order to ensure that it is applied directly to the skin and not on the hair, as this could lead to a lower bioavailability of the active substance and thus, to a reduced activity.

Shampooing and immersion of the animals in water directly after treatment may reduce the efficacy of the product. Treated animals therefore should not be bathed until the solution has dried.

It is recommended to treat all the animals living in the same household concomitantly.

When infection with tapeworms has been confirmed, concomitant treatment against intermediate hosts, such as fleas and lice, should be discussed with a veterinarian to prevent re-infection.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. The use of this product should take into account local epidemiological information about susceptibility of the target helminths.

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.
Apply only to the skin surface and on intact skin.
It is important to apply the veterinary medicinal product to a skin area where the cat cannot lick it off: on the neck or between shoulders.
Avoid the treated cats or other animals in the household licking the site of application while it is wet.
Care should be taken to avoid the contents of the pipette coming into contact with the eyes or mouth of the recipient animal.
For severely debilitated or heavily infested cats, use only according to a benefit/risk assessment by the responsible veterinarian.

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 pipette coming into contact with the skin, eyes or 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.
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. Pregnant women, women intending to conceive and breastfeeding women should not administer the product.
Do not stroke or groom animals until area of application is dry (at least one hour after application).
Wash hands thoroughly after use.
Do not eat, drink or smoke during application.
Keep the product in the outer carton until ready to use.
Store away from food, drink and animal feeding stuffs.

Other precautions
The solvent in the veterinary medicinal product may damage various materials such as plastics, leather or fabrics.Avoid contact of the product or the wet application area (s) with such materials.

Use during pregnancy and lactation:
Laboratory studies with praziquantel in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. The safety of praziquantel was established in pregnant and lactating queens. However laboratory studies with the excipient N-methyl-2pyrrolidone in rabbits and rats have shown evidence of teratogenic, foetotoxic, maternotoxic and reprotoxic effects, therefore use of the product is not recommended during pregnancy.

Interaction with other medicinal products and other forms of interaction: None known.

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

Incompatibilities:
Not applicable.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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.