LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prazpronto 40 mg Spot-on solution for medium cats
Praziquantel

2. STATEMENT OF ACTIVE SUBSTANCES

Praziquantel 40 mg per pipette

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 x 1.0 ml
2 x 1.0 ml
3 x 1.0 ml
4 x 1.0 ml
6 x 1.0 ml

5. TARGET SPECIES

Cats.

6. INDICATION(S)

For the treatment of tapeworms infection in cats weighing from 2.5 to 5 kg: *Dipylidium caninum* (immature and adult), *Taenia* spp (immature and adult) and *Echinococcus multilocularis*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

The need for and frequency of re-treatment should be determined by your veterinarian.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

For external use only
Please read the package leaflet before use for full instructions, including user warnings.
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 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.
People with known hypersensitivity to Praziquantel should avoid contact with the veterinary medicinal product.
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.

Do not use in cats weighing less than 2.5 kg.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Use of the product in pregnant animals is not recommended.
For severely debilitated or heavily infested cats, use only according to a benefit/risk assessment by the responsible veterinarian.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL 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

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)

Vm 08749/4091

17. MANUFACTURER'S BATCH NUMBER

BN{number}

PARTICULARS TO APPEAR ON THE SMALL IMMEDIATE PACKAGE UNIT

{Label for 1.0 ml pipette}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prazpronto 40mg Spot-on solution for medium cats
Praziquantel

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Praziquantel 40 mg

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

1.0 ml

4. ROUTE 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

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{SACHET TEXT}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prazpronto 40mg Spot-on solution for medium cats
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.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Prazpronto 40mg Spot-on solution for medium cats

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

Prazpronto 40 mg Spot-on solution for medium cats
Praziquantel

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

Each 1.0 ml pipette contains:

Active substance:
Praziquantel 40 mg

Excipients:

Butylhydroxytoluene (E321) 1.0 mg

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

4. INDICATION(S)

For the treatment of tapeworms infection in cats weighing from 2.5 to 5 kg: *Dipylidium caninum* (immature and adult), *Taenia* spp (immature and adult) and *Echinococcus multilocularis*

5. CONTRAINDICATIONS

Do not use on cats weighing less than 2.5 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 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:
Spot-on solution for external use only. Animals should be weighed to ensure accurate dosing.

Dosage and Treatment Schedule

The minimum dose rate is 8 mg/kg bodyweight, which equates to 1 pipette of 1 ml for a medium cat (> 2.5 – 5 kg) corresponding to a dose rate of 8-16 mg/kg bw.

The need for and frequency of re-treatment should be determined by your veterinarian.

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.

To minimise the possibility of run-off during application, it is advised that the application should be performed slowly to allow absorption.

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 and moisture.
Store away from food, drink and animal feeding stuffs.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Do not remove the pipette from the sachet until ready for use.

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 the cestode *Dipylidium caninum* 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.

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.
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 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.
People with known hypersensitivity to Praziquantel should avoid contact with the veterinary medicinal product.
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
Echinococcus 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.
Keep recently treated pets away from varnished, polished, plastic or leather surfaces.

Use during pregnancy and lactation:
Laboratory studies with praziquantel in rats and rabbits have not produced any evidence of teratogenic, feototoxic 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:
Do not administer at the same time as other products containing praziquantel.

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

Incompatibilities:
Not applicable

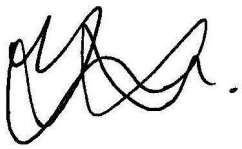
13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused 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

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.



Approved: 06 October 2020