SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prazpronto 60mg Spot-on solution for large cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1.5 ml pipette contains:

Active substance:
Praziquantel 60 mg

Excipient(s):
Butylhydroxytoluene (E321) 1.5 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 tapeworm infections in cats weighing from 5 kg to 7.5 kg: *Dipylidium caninum* (immature and adult), *Taenia* spp (immature and adult) and *Echinococcus multilocularis*

4.3 Contraindications

Do not use on cats weighing less than 5 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 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.

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 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.

iii) 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.

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, 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.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer at the same time as other products containing praziquantel.

4.9 Amount(s) to be administered and administration route

Spot-on solution for external use only. Animals should be weighed accurately prior to treatment.

Dosage and Treatment Schedule

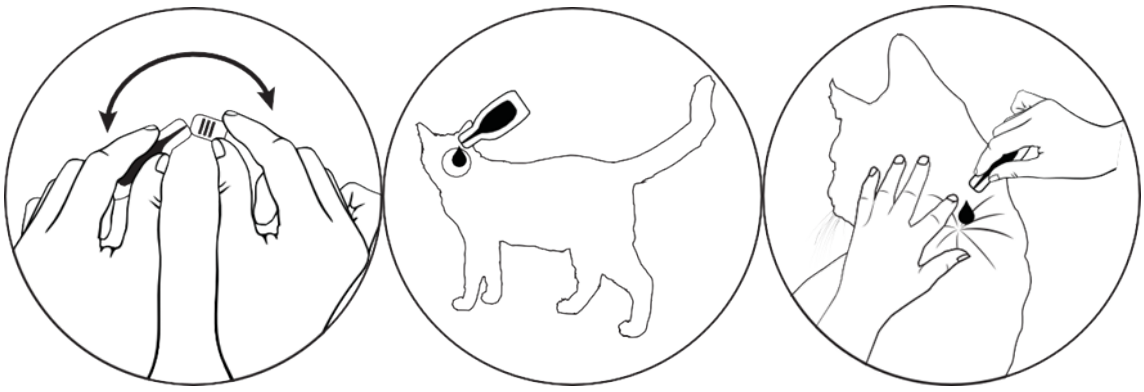
The minimum dose rate is 8 mg/kg bodyweight, which equates to 1 pipette of 1.5 ml for a large cat
(> 5 – 7.5 kg) corresponding to a dose rate of 8-12 mg/kg bw.
The need for and frequency of re-treatment should be determined by your veterinarian.

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. In larger cats (> 5 kg) the content of the pipette should be applied over two spots at the base of the skull.

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 substance is very rapidly absorbed and distributed throughout the parasite. Both *in vivo and in vitro* studies have shown that praziquantel causes severe damage to the parasite integument, resulting in contraction and paralysis. There is an almost instantaneous tetanic contraction of the parasite musculature and a rapid vacuolisation of the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, particularly calcium.

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 and moisture.

Store away from food, drink and animal feeding stuffs.

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

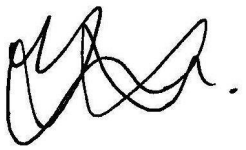
Vm 08749/4092

9. DATE OF FIRST AUTHORISATION

06 October 2020

10. DATE OF REVISION OF THE TEXT

October 2020



Approved: 06 October 2020