A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Itch Wormer Spot On Plus 60 mg/15 mg Spot-on Solution for Medium Cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.70 ml pipette contains:
Active substances:

Praziquantel	60 mg
Emodepside	15 mg

3. PACKAGE SIZE

1 x 0.70 ml
2 x 0.70 ml
3 x 0.70 ml
6 x 0.70 ml

4. TARGET SPECIES

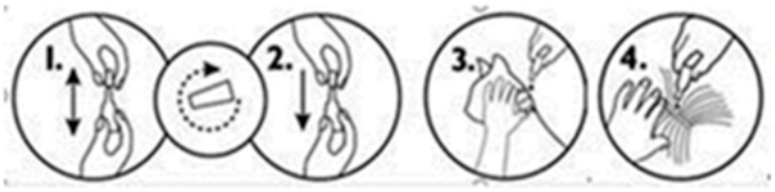
MEDIUM CATS
≥ 2.5 – 5 kg

5. INDICATIONS

Treatment of mixed infections by roundworms and tapeworms.

6. ROUTES OF ADMINISTRATION

Spot-on use for external application to the skin.



7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store in the original packaging (PP pipettes inserted into laminated aluminium bags) in order to protect from moisture.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

14. MARKETING AUTHORISATION NUMBERS

Vm 01656/5114 (GB)
Vm 01656/3114 (NI)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{BAG}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Itch Wormer Spot On Plus

> 2.5 – 5 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

praziquantel/emodepside
60 mg/15 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

KRKA

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{PIPETTE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Itch Wormer Spot On Plus

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

> 2.5 – 5 kg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

KRKA

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Itch Wormer Spot On Plus 30 mg/7.5 mg Spot-on Solution for Small Cats
Itch Wormer Spot On Plus 60 mg/15 mg Spot-on Solution for Medium Cats
Itch Wormer Spot On Plus 96 mg/24 mg Spot-on Solution for Large Cats

2. Composition

Each unit dose (pipette) contains:

Active substances:

Itch Wormer Spot On Plus	**Pipette (ml)**	**Praziquantel**	**Emodepside**
Small cats (≥ 0.5 – 2.5 kg)	0.35	30 mg	7.5 mg
Medium cats (>2.5 – 5 kg)	0.70	60 mg	15 mg
Large cats (> 5 – 8 kg)	1.12	96 mg	24 mg

Excipients:
Butylhydroxyanisole (E320) 5.4 mg/ml

Clear, colourless to yellow or to brown solution.

3. Target species

Small cats (Equal to/greater than 0.5 – 2.5 kg).
Medium cats (Greater than 2.5 – 5 kg).
Large cats (Greater than 5 – 8 kg).

4. Indications for use

For the treatment of mixed parasitic infections in cats caused by roundworms and tapeworms of the following species:

Roundworms (Nematodes):
Toxocara cati (mature adult, immature adult, L4 and L3)
Toxocara cati (L3 larvae) – treatment of queens during late pregnancy to prevent lactogenic transmission to the offspring

Toxascaris leonina (mature adult, immature adult and L4)
Ancylostoma tubaeforme (mature adult, immature adult and L4)

Tapeworms (Cestodes):
Dipylidium caninum (mature adult and immature adult)
Taenia taeniaeformis (adult)
Echinococcus multilocularis (adult)

The veterinary medicinal product is only indicated when use against nematodes and cestodes is indicated at the same time.

5. Contraindications

Do not use in kittens under 8 weeks of age or weighing less than 0.5 kg.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

Special warnings:
Shampooing or immersion of the animal in water directly after treatment may reduce the efficacy of the veterinary medicinal product. Treated animals therefore should not be bathed until the solution has dried.

In the absence of the risk of co-infection with nematodes and cestodes, a narrow spectrum product should be used.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

Special precautions for safe use in the target species:
Apply only to the skin surface and on intact skin. Do not administer orally or parenterally.
Avoid the treated cat or other cats in the household licking the site of application while it is wet.
There is limited experience on the use of the veterinary medicinal product in sick and debilitated animals. Therefore, the product should not be administered to these animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal 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.
Avoid direct contact with application area while it is wet. Keep children away from treated animals during that time.
In case of accidental contact with the skin or eyes, wash off any skin contamination immediately with soap and water.
Rinse the affected eyes thoroughly with clean, fresh water.

People with known hypersensitivity to praziquantel should avoid contact with the veterinary medicinal product.
If skin or eye symptoms persist, or in case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Care should be taken not to allow children to have prolonged intensive contact (for example, by sleeping) with treated cats during the first 24 hours after application of the veterinary medicinal product.
Do not smoke, eat or drink during application.
Wash hands after use.

Other precautions:
The solvent in this veterinary medicinal product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the WOAH, specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

Pregnancy and lactation:
Can be used during pregnancy and lactation. See section »Dosage for each species, routes and method of administration.«

Interaction with other medicinal products and other forms of interaction:
Emodepside is a substrate for P-glycoprotein. Co-treatment with other drugs that are P-glycoprotein substrates/inhibitors (for example, ivermectin and other antiparasitic macrocyclic lactones, erythromycin, prednisolone and cyclosporine) could give rise to pharmacokinetic drug interactions. The potential clinical consequences of such interactions have not been investigated. If your cat is receiving any medications, please contact your vet to discuss this before applying the product. Similarly, please inform your vet that you are using this product if s/he provides your cat with any medication.

Overdose:
Salivation, vomiting and neurological signs (tremor) were observed occasionally when the veterinary medicinal product was administered at up to 10 times the recommended dose in adult cats and up to 5 times the recommended dose in kittens. These symptoms were thought to occur as a result of the cat licking the application site. The symptoms were completely reversible.
There is no known specific antidote.

Major incompatibilities:
None known.

7. Adverse events

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Systemic disorders (anorexia, lethargy) Digestive tract disorders (salivation (drooling), vomiting, diarrhoea)[1] Neurological disorders (e.g. ataxia (incoordination), tremor)[1,2,3] Behavioural disorders (e.g. hyperactivity, anxiety, vocalisation) Application site disorders (alopecia (hair loss), pruritus (itchiness) and/or inflammation)[3]

[1]As a result of the cat licking the application site immediately after treatment.
[2]Mild signs.
[3]Transient signs.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Spot-on use for external application to the skin.

Dosage and Treatment Schedule

The recommended minimum doses are 12 mg praziquantel / kg body weight and 3 mg emodepside / kg body weight, equivalent to 0.14 ml of the veterinary medicinal product / kg body weight.

Body weight of the cat (kg)	Pipette size/volume (ml) to be used	Praziquantel (mg/kg body weight)	Emodepside (mg/kg body weight)
Equal to/greater than 0.5-2.5	0.35	12 – 60	3 – 15
Greater than 2.5-5	0.70	12 – 24	3 – 6
Greater than 5-8	1.12	12 – 19.2	3 – 4.8

Greater than 8	Use an appropriate combination of pipettes.

To ensure a correct dosage, body weight should be determined as accurately as possible. Underdosing could result in ineffective use and may favour resistance development.

For the treatment of roundworms and tapeworms a single administration per treatment is effective.

For the treatment of queens to prevent transmission of *Toxocara cati* (L3 larvae) through the milk to the offspring, a single administration per treatment approximately seven days prior to expected parturition (birthing) is effective.

The need for and frequency of re-treatments should be based on professional advice and should take into account individual risk factors (the local epidemiological situation and the animal's lifestyle).

9. Advice on correct administration

1. Remove the pipette from its packaging. Hold the pipette in an upright position, twist and pull the cap off.
2. Turn the cap around and place the other end of the cap back on the pipette. Push and twist the cap to break the seal, then remove the cap from the pipette.
3. Part the coat on the animal's neck at the base of the skull until the skin is visible.
4. Place the tip of the pipette onto the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot. Avoid contact between the veterinary medicinal product and your fingers.

Application at the base of the skull will minimise the opportunity for the animal to lick the veterinary medicinal product off.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.

Store in the original packaging (PP pipettes inserted into laminated aluminium bags) in order to protect from moisture.
Do not use this veterinary medicinal product after the expiry date which is stated on the labels and carton after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as emodepside may be dangerous for fish and other aquatic organisms.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01656/5113 (GB) – Small Cats
Vm 01656/3113 (NI) – Small Cats

Vm 01656/5114 (GB) – Medium Cats
Vm 01656/3114 (NI) – Medium Cats

Vm 01656/5115 (GB) – Large Cats
Vm 01656/3115 (NI) – Large Cats

0.35 ml, 0.70 ml and 1.12 ml per pipette; cardboard box containing 1, 2, 3 or 6 pipettes.

Not all pack sizes may be marketed.

15. 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.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Local representatives and contact details to report suspected adverse reactions:
KRKA UK Ltd
United Kingdom
Tel: 02071 646 156
info.uk@krka.biz

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

17. Other information

NFA-VPS

For animal treatment only.

Approved 12 December 2025
Gavin Hall