B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Beaphar Worm 30 mg/7.5 mg spot-on solution for small cats
Beaphar Worm 60 mg/15 mg spot-on solution for medium cats
Beaphar Worm 96 mg/24 mg spot-on solution for large cats

2. Composition

Each unit dose (pipette) contains:

Active substances:

Beaphar Worm spot-on solution	**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

Cats
(≥ 0.5 – 2.5 kg)
(> 2.5 – 5 kg)
(> 5 – 8 kg)

4. Indications for use

For cats with, or at risk from, mixed parasitic infections caused by roundworms and tapeworms targeted by each of the combined active substance. The veterinary medicinal product is only indicated when use against roundworms and tapeworms is required at the same time.

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)

5. Contraindications

Do not use in kittens under 8 weeks of age or cats weighing less than 0.5 kg (the veterinary medicinal product for small cats), 2.5 kg (the veterinary medicinal product for medium cats), 5 kg (the veterinary medicinal product for large cats).
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

Special warnings:
Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of based on its epidemiological features, for each individual animal.
In the absence of risk of co-infection , a narrow spectrum product should be used.
The possibility that other animals in the same household can be a source of re-infection with nematodes and/or cestodes should be considered, and these should be treated as necessary with an appropriate product.
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.
A resistance of *Dipylidium caninum* to praziquantel has been reported in dogs.
The use of this product should take into account local information about susceptibility of the target parasites, where available.
It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method.
Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.
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.

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 veterinary medicinal 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.
In case of accidental spillage onto skin, wash off immediately with soap and water.
If the veterinary medicinal product accidentally gets into contact with the eyes, they should be thoroughly flushed with plenty of water.
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.

Avoid direct contact with application area while it is wet. 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.

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 veterinary medicinal product. Similarly, please inform your vet that you are using this veterinary medicinal 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):	Application site alopecia[1], application site pruritus[1], application site inflammation[1] Salivation[2], vomiting[2], diarrhoea[2], anorexia Neurological disorders (mild and transient)[2, 3] Behavioural disorders[4]

[1]Transient.
[2]These effects are thought to occur as a result of the cat licking the application site immediately after treatment.
[3]Such as ataxia or tremor.
[4]Such as hyperactivity, anxiety and vocalisation.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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 its local representative using the contact details at the end of this leaflet, or via your national reporting system:

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

Spot-on use.

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.

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)
≥0.5-2.5	0.35	12 – 60	3 – 15
>2.5-5	0.70	12 – 24	3 – 6
>5-8	1.12	12 – 19.2	3 – 4.8
Over 8	Use an appropriate combination of pipettes designated for different weight ranges to achieve the correct dose.		

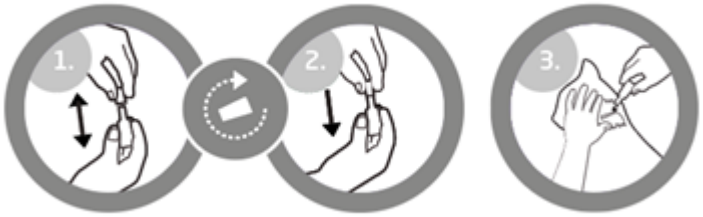
For the treatment of roundworms and tapeworms a single administration per treatment is effective.

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

9. Advice on correct administration

For external use only.

1. Remove one 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. 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.

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

This veterinary medicinal product does not require any special temperature storage conditions.

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 or household waste.

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 applicable national collection systems. 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

Cardboard box containing 1, 2, 3 or 6 pipettes, each pipette containing 0.35 ml, 0.70 ml or 1.12 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Local representatives and contact details to report suspected adverse events:

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

17. Other information