Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

~~Novospot Worming Solution 30 mg/7.5 mg Spot-on Solution for Small Cats~~
~~Novospot Worming Solution 60 mg/15 mg Spot-on Solution for Medium Cats~~
~~Novospot Worming Solution 96 mg/24 mg Spot-on Solution for Large Cats~~
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

Date Created: **July 2025**

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	~~Novospot Worming Solution 30 mg/7.5 mg Spot-on Solution for Small Cats, Spot-on solution~~ ~~Novospot Worming Solution 60 mg/15 mg Spot-on Solution for Medium Cats, Spot-on solution~~ ~~Novospot Worming Solution 96 mg/24 mg Spot-on Solution for Large Cats, Spot-on solution~~ 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
Applicant	KRKA, d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto, Slovenia
Active substance	Emodepside Praziquantel
ATC Vetcode	QP52AA51
Target species	Cats
Indication for use	For cats suffering from, or at risk from, mixed parasitic infections caused by roundworms, tapeworms and lungworms 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) Lungworms: *Aelurostrongylus abstrusus* (adult) The products are only indicated when use against nematodes and cestodes is indicated at the same time.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended.
Date of conclusion of the procedure	04/06/2025

I. SCIENTIFIC OVERVIEW

These are generic applications in accordance with Article 8 of VMRs 2013 (Schedule 1, Para 10) as amended, for authorisations in Great Britain (GB) and Northern Ireland (NI). The reference products are Profender Spot-on Solutions for Small, Medium and Large Cats (3 x product strengths), which have been authorised in the UK and EU since July 2005. Bioequivalence of the products with the reference products was established based on appropriate justification. The applicant claimed a waiver from the requirement to conduct an *in vivo* bioequivalence study, based on section 7.1b) of the current EMA Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/2000-Rev.4).

Itch Wormer Spot On Plus 30 mg/7.5 mg Spot-on Solution for Small Cats ~~Novospot Worming Solution 30 mg/7.5 mg Spot-on Solution for Small Cats~~ contains 30 mg of praziquantel and 7.5 mg emodepside per 0.35 ml pipette. Itch Wormer Spot On Plus 60 mg/15 mg Spot-on Solution for Medium Cats ~~Novospot Worming Solution 60 mg/15 mg Spot-on Solution for Medium Cats~~ contains 60 mg praziquantel and 15 mg emodepside per 0.70 ml pipette. Itch Wormer Spot On Plus 96 mg/24 mg Spot-on Solution for Large Cats ~~Novospot Worming Solution 96 mg/24 mg Spot-on Solution for Large Cats~~ contains 96 mg praziquantel and 24 mg emodepside per 1.12 ml pipette.

The products are indicated for cats suffering from, or at risk from, mixed parasitic infections caused by roundworms, tapeworms and lungworms of the specific species referenced in the SPC. For each product range and pipette strength, the proposed recommended minimum doses are 12 mg praziquantel/kg bodyweight and 3 mg emodepside/kg bodyweight, equivalent to 0.14 ml of the product/kg bodyweight.

The distribution category for each product is NFA-VPS, a veterinary medicinal product that is for a non-food animal and can be supplied by a Veterinarian, Pharmacist or a Suitably Qualified Person.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released on the market. It has been shown that the product can be safely used in the target species, any reactions observed are indicated in the SPC[1]. The product is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy[2] of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains praziquantel and emodepside and the excipients butylhydroxyanisole (E320), isopropylidene glycerol and lactic acid.

The container/closure system consists of a polypropylene pipette with a high-density polyethylene closure with a spike packed in aluminium bag. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence of preservative are justified.

The product is an established pharmaceutical form, and its development is adequately described, in accordance with the relevant regulatory guidelines.

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant regulatory guidelines.

II.C. Control of Starting Materials

The active substances are praziquantel and emodepside, both established active substances. Praziquantel is described in the European Pharmacopoeia, certified by CEP (Certificate of Suitability) and emodepside is supported by an ASMF (Active Substance Master File). The active substances are manufactured in accordance with the principles of good manufacturing practice.

[1] SPC – Summary of product Characteristics.
[2] Efficacy – The production of a desired or intended result.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

The excipients lactic acid and butylhydroxyanisole (BHA) are well known pharmaceutical ingredients covered by Ph. Eur. monographs. The applicant provided adequate data on isopropylidene glycerol for its use as an excipient.

Packaging materials are acceptable and comply with Ph. Eur.

II.C.4. Substances of Biological Origin

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product. Satisfactory validation data for the analytical methods have been provided. Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification. Control tests on the finished product are those appropriate for this type of dosage form.

II.F. Stability

Stability data on the active substances have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

The shelf life for each of the products, as packaged for sale, is 2 years. The products do not require any special temperature storage conditions, and they should be stored in the original packaging (PP pipettes inserted into laminated aluminium bags), in order to protect from moisture.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

Due to the legal basis of the applications, no pharmacological or toxicological data were submitted, which is acceptable. Bioequivalence of the products to the reference products was established, based on appropriate justification.

Warnings and precautions as listed on the product literature are generally the same as those of the reference product and are adequate to ensure safety of the product to users/the environment/consumers. One addition was to include the advice to use the entire contents of the pipette immediately once opened and dispose of any used pipettes immediately after use.

III.A Safety Documentation

Pharmacological Studies

Bioequivalence of the products to the reference products was accepted.

Praziquantel is a pyrazinoisoquinoline derivative effective against certain tapeworms. It is rapidly adsorbed via the surface of the parasites and acts primarily by changing the Ca++ permeability of the parasite membranes. This results in severe damage to the parasite, contraction and paralysis, disruption of metabolism and finally leads to the death of the parasite.

Emodepside is a semi-synthetic compound belonging to the new chemical group of depsipeptides. It is active against roundworms (ascarids and hookworms). It acts at the neuromuscular junction by stimulating presynaptic receptors which results in paralysis and death of the parasites.

After topical application of an equivalent veterinary medicinal product to cats at the minimum therapeutic dose of 0.14 ml/kg bodyweight, maximum serum concentrations were reached at 18.7 (± 47) hours after application for praziquantel and at 3.2 (± 2.7) days for emodepside. Both active substances are slowly eliminated from the serum with a half-life of 4.1 (± 1.5) days for praziquantel and 9.2 (± 3.9) days for emodepside.

Studies in many different species show that praziquantel is rapidly metabolised in the liver and primarily eliminated renally. After oral application in the rat, emodepside is distributed to all organs and mainly eliminated faecally.

User Safety

A user risk assessment was provided in compliance with the relevant guideline which shows that the products are not considered to present an unacceptable risk to the user when used as recommended.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore, the following applicant's user recommendations are appropriate:

- Do not smoke, eat or drink during application.
- Avoid direct contact with application area while it is wet. Keep children away from treated animals during that time.
- Once opened, use the entire contents of the pipette immediately.
- Dispose of any used pipettes immediately after use.
- Wash hands after use.
- In case of accidental spillage onto skin, wash off immediately with soap and water.
- If the veterinary medicinal product accidentally gets into 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.
- 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.

Environmental Safety

The product will only be used in non-food animals and as a result environmental exposure will be low. A Phase II ERA was not required.

IV. CLINICAL DOCUMENTATION

As these are generic applications, and bioequivalence with the reference product has been accepted, efficacy studies are not required. The efficacy claims, dosing regimens, and pharmacology for these products are equivalent to those of the reference products.

Resistance

The applicant conducted an appropriate literature review and has not identified any reports of resistance against the active substances emodepside and praziquantel, in the proposed feline target parasites, in the European region.

Adequate warnings and precautions appear on the product literature.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics the benefit/risk profile of the products is favourable.

MODULE 4

POST- AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)