PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box, pack sizes of 1, 3, 4, 6 or 15 applicators}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NexGard Combo spot-on solution for cats < 2.5 kg

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose:

Esafoxolaner	3.60 mg
eprinomectin	1.20 mg
praziquantel	24.90 mg

3. PACKAGE SIZE

1 x 0.3 ml
3 x 0.3 ml
6 x 0.3 ml
15 x 0.3 ml

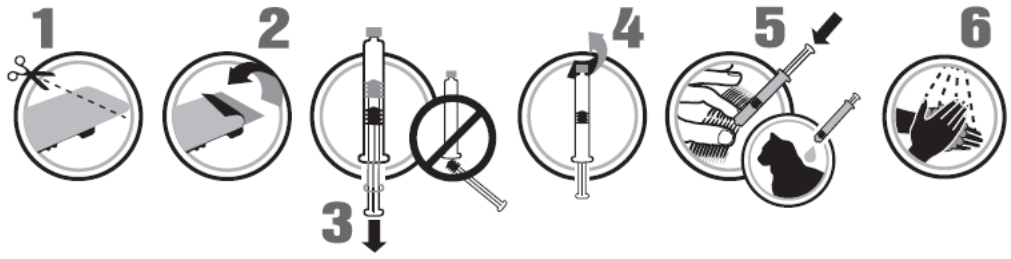
4. TARGET SPECIES

Cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spot-on use.
External use only
Avoid contact of the product with your eyes.



7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Keep the unused applicator in the blister package in order to protect from light.
Used applicators should be disposed of immediately.
Do not remove from blister until required for use.
Keep the blister in the outer carton.

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

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBER

Vm 61700/5026

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NexGard Combo < 2.5 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

0.3 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Applicator}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NexGard Combo

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

0.3 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

NexGard Combo spot-on solution for cats < 2.5 kg
NexGard Combo spot-on solution for cats 2.5-7.5 kg

2. Composition

Each spot-on applicator delivers:

Active substances:

NexGard Combo	Volume of unit dose (ml)	Esafoxolaner (mg)	Eprinomectin (mg)	Praziquantel (mg)
Cats 0.8-<2.5 kg	0.3	3.60	1.20	24.90
Cats 2.5-<7.5 kg	0.9	10.80	3.60	74.70

Excipients:
Butylhydroxytoluene (E321) .....1 mg/ml

Clear, colourless to light yellow to light brown solution.

3. Target species

Cats.

4. Indications for use

For cats with, or at risk from mixed infections by cestodes, nematodes and ectoparasites. The veterinary medicinal product is exclusively indicated when all three groups are targeted at the same time.

Ectoparasites
- Treatment of infestations by fleas (*Ctenocephalides felis)*. One treatment provides immediate and persistent flea killing activity for one month.
- The product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).
- Treatment of infestations by ticks. One treatment provides immediate and persistent tick killing activity against *Ixodes scapularis* and *Ixodes hexagonus* for one month and against *Ixodes ricinus* for five weeks.
- Persistent tick killing activity from 7 days to five weeks after treatment against *Rhipicephalus sanguineus*.
- Treatment of infestations by ear mites (*Otodectes cynotis*).
- Treatment of Notoedric mange (caused by *Notoedres cati*).

Cestodes
Treatment of infections with tapeworms (*Dipylidium caninum*, *Taenia taeniaeformis*, *Echinococcus multilocularis, Joyeuxiella pasqualei*, and *Joyeuxiella fuhrmanni*).

Nematodes
- Prevention of heartworm disease (*Dirofilaria immitis*) for one month.
- Treatment of infections with gastrointestinal nematodes (L3, L4 larvae and adults of *Toxcara cati*, L4 larvae and adults of *Ancylostoma tubaeforme* and *Ancylostoma ceylanicum*, and adult forms of *Toxascaris leonina* and *Ancylostoma braziliense*).
- Treatment of infections with feline lungworms (L4 larvae and adults of *Troglostrongylus brevior*, L3, L4 larvae and adults of *Aelurostrongylus abstrusus*).
- Treatment of infections with vesical worms (*Capillaria plica*).
- Treatment of infections with eye worms (Thelazia callipaeda).

5. Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

Special warnings:
When applying the veterinary medicinal product, special attention should be paid to long hair breeds in order to ensure that the product is applied directly to the skin and not on the hair, as this could lead to a lower bioavailability of the active substance.

Ticks and fleas need to start feeding on the cat to become exposed to esafoxolaner; therefore, the risk of transmission of arthropod borne diseases cannot be excluded.

Cats in areas endemic for heartworm, or those which have travelled to endemic areas, may be infected with adult heartworms. Although the veterinary medicinal product may be safely administered to cats infected with adult heartworms, no therapeutic effect against adult Dirofilaria immitis has been established. It is, therefore, recommended that all cats 6 months of age or more, living in areas endemic for heartworm, should be tested for existing adult heartworm infection before being treated with the product for heartworm disease prevention.

Tapeworm infection may reoccur unless control of intermediate hosts such as fleas, mice etc. is undertaken. Some cats with patent Joyeuxiella spp. or Dipylidium caninum infections may nevertheless harbour a high proportion of juvenile worms, which may be less susceptible to the product; therefore, a post-treatment follow-up is recommended in case of such infections.

In certain individual cats Notoedres cati infestation may be severe or complicated by bacterial infections. In these severe cases concomitant treatment may be necessary.

Parasite resistance to any particular class of antiparasitics included in the fixed combination product may develop following repeated use of an antiparasitic of those classes over an extended period of time. Therefore, epidemiological information about

current susceptibility of the target species should be taken into account in order to limit the possibility of a future selection for resistance.

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 infestation 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 fleas or worms should be considered, and these should be treated as necessary with an appropriate product.

Avoid shampooing the animal within the 2 days following application because the effectiveness of the product in this case has not been tested.

To reduce re-infestation from emergence of new fleas, it is recommended that all cats in a household are treated. Other animals living in the same household should also be treated with a suitable product.

All stages of fleas can infest the cat’s basket, bedding and regular resting areas such as carpets and soft furnishings. In case of massive flea infestation and at the beginning of the control measures, these areas should be treated with a suitable environmental product and then vacuumed regularly.

Special precautions for safe use in the target species:
Spot-on application only. Do not inject, do not administer orally or via any other route. Avoid contact with the cat's eyes. If accidental ocular contact occurs, flush the eyes immediately with clean water. If eye irritation persists, seek veterinary advice.

It is important to apply the veterinary medicinal product to a skin area where the cat cannot lick it off: on the midline of the neck, between the base of the skull and the shoulder blades. Ensure that animals do not lick each other until the treated area is no longer noticeable. Oral ingestion of the veterinary medicinal product has been observed to lead to hypersalivation.

The safety of the veterinary medicinal product has not been tested in kittens under 8 weeks of age. The product is for use in cats weighing at least 0.8 kg and from 8 weeks of age.

The veterinary medicinal product should exclusively be used in confirmed mixed infections or where cats are at significant risk of such mixed infection with ectoparasites and nematodes (including for heartworm disease prevention) and where concurrent treatment against cestodes is indicated. In the absence of risk of co-infestation, the use of a narrow spectrum parasiticide should be considered as a first line therapy.

The rationale for prescription and frequency of use should be tailored to the individual needs of the cat, based on clinical assessment, the cat’s lifestyle and on the local

epidemiological situation (including zoonotic risks, where relevant) in order to address exclusively situations of mixed infections/risk of infection.

The veterinary medicinal product should not be used in other cats without prior veterinary consultation.

Target animal safety has not been evaluated beyond 6 consecutive monthly treatments and accumulation of esafoxolaner and eprinomectin was observed up to the 5th monthly administration (see also overdose section). Repeated treatments beyond 6 consecutive months should be restricted to limited individual situations (see relevant section for treatment guidance), with a minimum treatment interval of 4 weeks, according to a benefit-risk evaluation by the responsible veterinarian

Echinococcosis represents a hazard for humans, and is a notifiable disease to the World Organisation for Animal Health (WOAH). In case of echinococcosis, specific guidelines on the treatment and follow up and on the safeguard of persons have to be followed. Experts or institutes of parasitology should be consulted.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not smoke, drink or eat during application.
Wash hands immediately after use.
Used applicators should be disposed of immediately and not left within the sight or reach of children.

Avoid contact of the applicator content with the fingers. If this occurs, wash off with soap and water. This veterinary medicinal product can cause eye irritation, which might be in exceptional cases severe. In case of accidental eye exposure, flush the eyes immediately and thoroughly with water. Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing. Seek medical advice and show the package leaflet or the label to the physician.

Ensure that the treated area is no longer noticeable before resuming contact with the site of application. Children should not be allowed to play with treated animals until the application site is no longer noticeable and it is recommended that recently treated animals do not sleep with owners, especially children. It is recommended to treat animals in the evening to reduce contact with people after treatment.

People with a known hypersensitivity to esafoxolaner, eprinomectin or praziquantel or to any of the excipients should avoid contact with the veterinary medicinal product.

Since foetotoxic and teratogenic effects are described in laboratory animals after significant daily exposure to glycerol formal, pregnant women should wear gloves during the administration to avoid direct contact with the product.

Pregnancy and lactation:
Can be used in pregnant and lactating queens.

Fertility:
Can be used in breeding queens.

The safety of the veterinary medicinal product has not been established in breeding male cats. Laboratory studies in rats and rabbits have not produced any evidence of adverse effects of the active substances on the reproductive capacity in males. In breeding males, use only according to the benefit-risk assessment by the prescribing veterinarian.

Overdose:
Safety has been evaluated with up to 5 times the maximum recommended dose in healthy kittens aged 8 weeks and older treated up to 6 times at 4-week intervals. At 3 times the maximum recommended dose, no undesirable effects were observed. At 5 times the maximum recommended dose, a single severe adverse neurological reaction (ataxia, disorientation, apathy, tremors, hypothermia and pupil dilation) was observed after the third treatment and was reversible following washing of the application site, emergency measures and symptomatic treatment. In some animals, at 5 times the maximum recommended dose, dark red subcutaneous areas at the skin treatment sites were observed.

7. Adverse events

Cats:

Uncommon (1 to 10 animals / 1 000 animals treated):
Hypersalivation[1] (increased salivation), diarrhoea[1], emesis[1] (vomiting), application site alopecia[1,2] (hair loss), application site pruritus[1,2] (itching), lethargy[1] (decreased activity) and anorexia[1] (appetite loss).

[1] Mostly mild reactions, of short duration and self-limiting.
[2] Transient

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 at https://www.gov.uk/report-veterinary-medicine-problem.

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

For topical application onto the skin (spot-on use).

Dosage:
The recommended minimum doses are 1.44 mg esafoxolaner, 0.48 mg eprinomectin and 10 mg
praziquantel per kg bodyweight.

9. Advice on correct administration

Use the applicator size adapted to the weight of the cat (0.3 or 0.9 ml, see section

“statement of the active substance(s) and other ingredient(s)”). 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.

Method of administration:

1. Use scissors to cut the blister along the dotted line.
2. Then pull the lid away.
3. Remove the applicator from the package and point the rubber cap up. **Pull back the plunger moderately (approximately 1 cm).** Be careful not to take out the plunger.
4. Twist and pull off the cap.
5. Part the hair on the midline of the neck, between the base of the skull and the shoulder blades until the skin is visible. Place the tip of the applicator on the skin and **slowly apply** the entire content directly onto the skin in one spot. The product should be applied to dry skin on an area where the cat cannot lick it off. In long hair breeds, special attention should be paid to apply the product onto the skin, and not on the hair to ensure optimal efficacy.
6. Wash your hands after use.

Treatment schedule:
For the treatment of infestations with fleas and/or ticks and/or mites, and the concurrent treatment of gastrointestinal and/or pulmonary, and/or vesical nematodes, and/or eye worms, and cestodes, a single dose of the product should be applied. The need for and frequency of re-treatment(s) should be in accordance with the advice of the prescribing veterinarian and should take into account the local epidemiological situation and the animal’s lifestyle (e.g. outdoors access). See also section “special warning(s)”.

Areas which are not endemic for heartworm:
Cats not exposed to a permanent risk of heartworm infection should be treated according to a schedule prescribed by the veterinarian and adapted to each individual situation of re-infection/-infestation with parasites. Otherwise, a narrow spectrum product should be used to ensure sustainable treatment against relevant parasites.

Heartworm endemic areas:
Cats living in heartworm endemic areas and recognised as hunters might be treated at monthly intervals to ensure both appropriate heartworm disease prevention and treatment of potential re- infection with cestodes. Otherwise, a narrow spectrum product should be used for further treatment. Prevention of heartworm disease by killing *Dirofilaria immitis* larvae should start within 1 month after the first expected exposure to mosquitoes and should be continued until at least 1 month after the last exposure to mosquitoes.

Lungworm treatment:
No or little effect on the L1 larvae release of *A. abstrusus* in the faeces can be expected within approximately 2 weeks after treatment due to the transit period of L1 larvae from the lungs through the digestive tract.
Any faecal larval count to control effectiveness of treatment (and the decision if a second treatment with a narrow spectrum product is necessary) should, therefore, only be made two weeks after treatment at the earliest.

Ear mites
For ear mites, seek further veterinary examination 4 weeks after treatment to determine whether an additional treatment with a narrower spectrum product is necessary.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the unused applicator in the blister package in order to protect from light.
Used applicators should be disposed of immediately.
Do not remove from blister until required for use.
Keep the blister in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the 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 or an empty applicator should not enter water courses as esafoxolaner 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 subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 61700/5026
Vm 61700/5027

Cardboard box containing 1, 3, 4 or 15 blister(s) of 1 applicator (0.3 ml each).
Cardboard box containing 1, 3, 4, 6 or 15 blister(s) of 1 applicator (0.9 ml each).

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:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
4 Chemin du Calquet
31000 Toulouse
France

Local representatives and contact details to report suspected adverse reactions:

United Kingdom (Great Britain)
Boehringer Ingelheim Animal Health UK Limited
Bracknell, RG12 8YS, UK
Tel: + 44 1344 746957

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

17. Other information

Esafoxolaner kills fleas before egg production and therefore prevents the risk of household contamination.

POM-V	Veterinary medicinal product subject to prescription

For animal treatment only.

Gavin Hall
Approved: 02 October 2025