

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Box**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Endogard Plus XL Tablets for dogs  
*Praziquantel, pyrantel embonate, febantel*

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each tablet contains:  
Praziquantel                      175 mg  
Pyrantel embonate                504 mg  
Febantel                              525 mg

**3. PHARMACEUTICAL FORM**

Tablets

The tablets can be divided into equal halves.

**4. PACKAGE SIZE**

2 tablets  
4 tablets  
10 tablets  
12 tablets  
24 tablets  
30 tablets  
50 tablets  
60 tablets  
100 tablets  
102 tablets

**5. TARGET SPECIES**

Dogs (large and extra large size)

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.  
Oral use.

**8. WITHDRAWAL PERIOD**

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP:

**11. SPECIAL STORAGE CONDITIONS**

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Dispose of waste material in accordance with local requirements.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only.

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

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

KRKA, d.d., Novo mesto  
Šmarješka cesta 6  
8501 Novo mesto  
Slovenia

**16. MARKETING AUTHORISATION NUMBER**

Vm 01656/4018

**17. MANUFACTURER'S BATCH NUMBER**

Lot:

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Blister**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Endogard Plus XL Tablets for dogs  
*Praziquantel, pyrantel embonate, febantel*

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

KRKA, d.d., Novo mesto  
Šmarješka cesta 6  
8501 Novo mesto  
Slovenia

**3. EXPIRY DATE**

EXP:

**4. BATCH NUMBER**

Lot:

**5. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

**PACKAGE LEAFLET FOR:**

**Endogard Plus XL Tablets for dogs**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

KRKA, d.d., Novo mesto  
Šmarješka cesta 6  
8501 Novo mesto  
Slovenia

Manufacturer responsible for batch release:

KRKA - FARMA d.o.o., V. Holjevcina 20/E, 10450 Jastrebarsko, Croatia  
Virbac S.A., 1ere Avenue, 2065M, LID, 06516 Carros Cedex, France  
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Dehinel Plus XL Tablets for dogs (Czech Republic, Hungary, Estonia, Latvia, Lithuania, Poland, Romania, Slovenia, Slovakia)

*Praziquantel, pyrantel embonate, febantel*

Endogard Plus XL Tablets for dogs (United Kingdom, Austria, Belgium, Germany, Denmark, Greece, Ireland, Netherlands, Portugal)

*Praziquantel, pyrantel embonate, febantel*

Endogard Para Perros Grandes (Spain)

*Praziquantel, pyrantel embonate, febantel*

Endogard per cani grandi (Italy)

*Praziquantel, pyrantel embonate, febantel*

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Each tablet contains:

Praziquantel	175 mg
Pyrantel embonate	504 mg
Febantel	525 mg

Oval, biconvex tablets with beveled edges and scored on both sides. Slightly greenish-yellow.

The tablets can be divided into equal halves.

#### **4. INDICATION(S)**

For the treatment of mixed infestations with the following roundworms and tapeworms in adult dogs:

Nematodes:

Ascarids: *Toxocara canis*, *Toxascaris leonina* (late immature forms and mature forms)

Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults)

Cestodes:

Tapeworms: *Taenia* spp., *Dipylidium caninum*

#### **5. CONTRAINDICATIONS**

Do not use simultaneously with piperazine compounds

Do not use in animals with a known hypersensitivity to the active substance or to any of excipients.

Do not exceed the stated dosage when treating pregnant bitches.

#### **6. ADVERSE REACTIONS**

In very rare cases vomiting, with or without diarrhoea, may occur.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

#### **7. TARGET SPECIES**

Dogs (large and extra large size)

#### **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

For oral administration.

The recommended dose rates are: 15 mg/kg bodyweight febantel, 14.4 mg/kg pyrantel and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 35 kg bodyweight.

Tablets may be halved.

No restriction of access to food is required either before or after administration of the product.

The tablet(s) can be given directly to the dog or disguised in food.

## **9. ADVICE ON CORRECT ADMINISTRATION**

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible.

For the control of *Toxocara*, nursing bitches should be dosed 2 weeks after giving birth and every 2 weeks until weaning.

In the event of a heavy roundworm infestation, a repeat dose should be given after 14 days.

For routine control adult dogs should be treated every 3 months.

## **10. WITHDRAWAL PERIOD**

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.

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 WARNING(S)**

Special warnings for each target species:

Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum*. Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken.

Special precautions for use in animals:

This product is not recommended for use in dogs under 17.5 kg body weight.

Any part-used tablets should be discarded.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In the interests of good hygiene, persons administering the tablet directly to a dog or by adding it to the dog's food, should wash their hands afterwards.

In case of accidental ingestion, seek medical advice and show the package leaflet to the physician.

Use during pregnancy, lactation or lay:

Consult a veterinary surgeon before treating pregnant animals for roundworms.

The product may be used during lactation.

Do not use in bitches during the first two-thirds of pregnancy.

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with piperazine as the anthelmintic effects of pyrantel and piperazine (used in many worming products for dogs) may be antagonized.

Concurrent use with other cholinergic compounds can lead to toxicity.

Overdose (symptoms, emergency procedures, antidotes), if necessary:

The product is well tolerated in dogs. In safety studies, doses of up to five times the recommended dose gave rise to occasional vomiting.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION**

Print and perforated Alu-Alu blister: 2 tablets (1 blister with 2 tablets), in a box.

Print and perforated Alu-Alu blister: 4 tablets (2 blisters with 2 tablets), in a box.

Print and perforated Alu-Alu blister: 10 tablets (1 blister with 10 tablets), in a box.

Print and perforated Alu-Alu blister: 12 tablets (2 blisters with 6 tablets), in a box.

Print and perforated Alu-Alu blister: 24 tablets (4 blisters with 6 tablets), in a box.

Print and perforated Alu-Alu blister: 30 tablets (3 blisters with 10 tablets or 5 blisters with 6 tablets), in a box.

Print and perforated Alu-Alu blister: 50 tablets (5 blisters with 10 tablets), in a box.

Print and perforated Alu-Alu blister: 60 tablets (10 blisters with 6 tablets or 6 blisters with 10 tablets), in a box.

Print and perforated Alu-Alu blister: 100 tablets (10 blisters with 10 tablets), in a box.

Print and perforated Alu-Alu blister: 102 tablets (17 blisters with 6 tablets), in a box.

Not all pack sizes may be marketed.

\*Valid only for packaging of 60 tablets

1 per 35 kg

PRACTICE STAMP

Owner's name: .....  
.....  
Pet's name: .....  
.....  
Dosage:.....  
.....

Approved: 17 April 2019

