ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Outer Carton, 7.5 ml (or 20 ml) bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procox 0.9 mg/ml + 18 mg/ml oral suspension for dogs
emodepside/toltrazuril

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Active substances: emodepside 0.9 mg, toltrazuril 18 mg

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

7.5 ml
20 ml

5. TARGET SPECIES

For dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Read the package leaflet before use.
Oral use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 10 weeks.

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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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

Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06462/5005

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Bottle label, 7.5 (or 20ml) bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procox 0.9 mg/ml + 18 mg/ml oral suspension for dogs
emodepside/toltrazuril

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

0.9 mg/ml emodepside + 18 mg/ml toltrazuril.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

7.5 ml
20 ml

4. ROUTE(S) OF ADMINISTRATION

Shake well before use.
Oral use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use by…

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Procox 0.9 mg/ml + 18 mg/ml oral suspension 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:
Vetoquinol SA
34 Rue de Chene Sainte-Anne
Magny-Vernois
70200 Lure
France

Manufacturer responsible for batch release:
KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324
24106 Kiel
Germany

VETOQUINOL BIOWET Sp. z o.o.
Żwirowa 140
66-400 Gorzów Wlkp.,
Poland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procox 0.9 mg/ml + 18 mg/ml oral suspension for dogs

emodepside / toltrazuril

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 ml contains:

Active substances:

emodepside	0.9 mg
toltrazuril	18 mg

Excipients:

butylhydroxytoluene (E321; as antioxidant)	0.9 mg
sorbic acid (E200; as preservative)	0.7 mg

4. INDICATIONS

For dogs, when mixed parasitic infections caused by roundworms and coccidia of the following species are suspected or demonstrated:

Roundworms (Nematodes):
- *Toxocara canis* (mature adult, immature adult, L4)
- *Uncinaria stenocephala* (mature adult)
- *Ancylostoma caninum* (mature adult)
- *Trichuris vulpis* (mature adult)

Coccidia:
- *Isospora ohioensis* complex
- *Isospora canis*

Treatment will reduce the spread of *Isospora* infection but will not be effective against symptoms in already infected animals.

5. CONTRAINDICATIONS

Do not use in dogs/puppies which are under 2 weeks of age or weigh less than 0.4 kg.

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

6. ADVERSE REACTIONS

Slight and transient digestive tract disorders (e.g., vomiting or loose stools) may occur in very rare cases.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE, ROUTE AND METHOD OF ADMINISTRATION

Dose and Treatment Schedule

For oral use in dogs from 2 weeks of age and weighing at least 0.4 kg.

The recommended minimum dose is 0.5 ml/kg bodyweight (bw), equivalent to 0.45 mg emodepside / kg bw and 9 mg toltrazuril / kg bw.

Recommended dose volumes are given in the table below:

Weight [kg]	Dose [ml]
0.4	0.2
> 0.4 – 0.6*	0.3
> 0.6 – 0.8	0.4
> 0.8 – 1	0.5
> 1.0 – 1.2	0.6
> 1.2 – 1.4	0.7
> 1.4 – 1.6	0.8
> 1.6 – 1.8	0.9
> 1.8 – 2	1.0
> 2.0 – 2.2	1.1
> 2.2 – 2.4	1.2
> 2.4 – 2.6	1.3
> 2.6 – 2.8	1.4
> 2.8 – 3	1.5
> 3.0 – 3.2	1.6
> 3.2 – 3.4	1.7
> 3.4 – 3.6	1.8
> 3.6 – 3.8	1.9
> 3.8 – 4	2.0
> 4 – 5	2.5
> 5 – 6	3.0
> 6 – 7	3.5
> 7 – 8	4.0
> 8 – 9	4.5
> 9 – 10	5.0
> 10 kg: Continue with dose of 0.5 ml / kg bw	

***** = more than 0.4 and up to 0.6 kg

One treatment is generally sufficient to reduce the spread of *Isospora* infection. Repeated treatment is indicated only if mixed infections with coccidia and roundworms continue to be suspected (by the veterinarian) or demonstrated.

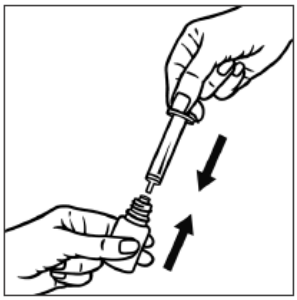
9. ADVICE ON CORRECT ADMINISTRATION

1. Shake well before use.
2. Remove screw cap. Use a standard disposable syringe with Luer nozzle for each treatment. To ensure precise dosing when treating dogs up to 4 kg, use a syringe with 0.1 ml graduations. For dogs weighing more than 4 kg a syringe with 0.5 ml graduations can be used. Place the syringe nozzle firmly into the opening of the bottle.

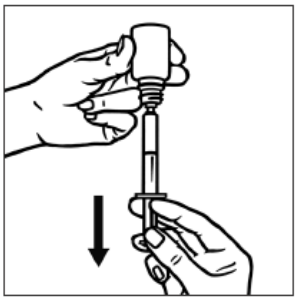
3. Then turn the bottle upside down, and withdraw the necessary volume. Turn the bottle back into an upright position before removing the syringe. Replace screw cap after use.

4. Give Procox into the mouth of the dog. Dispose of the syringe after treatment (as it is not possible to clean it).

1. Shake well before use.



2. Place syringe nozzle firmly into opening of the bottle.



3. Turn bottle upside down and withdraw necessary volume.

4. Give Procox into the dog's mouth.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the bottle: 10 weeks.
This veterinary medicinal product does not require any special storage conditions.

12. SPECIAL WARNINGS

Special warnings for each target species:

For Animal Treatment Only

Treatment will prevent the spread of *Isospora* infection but will not be effective against symptoms (e.g. diarrhoea) in already infected animals. Additional treatment (by a veterinarian) may be needed in animals with diarrhoea.

It is important to take hygienic measures to ensure the environment is as dry and clean as possible, in order to prevent reinfection from the environment.

Isospora oocysts are resistant to many disinfectants and can survive in the environment for a long time. The prompt removal of faeces (within 12 hours) reduces

the risk of transmission of infection. All dogs at risk of infection within the group should be treated at the same time.

As with any antiparasitic product, the frequent and long term use of anthelmintics or antiprotozoals may lead to the development of resistance. An appropriate treatment regimen established by a veterinarian will ensure adequate parasite control and reduce the likelihood of resistance developing.

Special precautions for use in animals:

Procox is not recommended to be used in dogs of Collie or related breeds that carry or are suspected to carry the mdr1 -/- mutation, because the tolerance of the product in mdr1 -/- mutant puppies has been shown to be lower than in other puppies.

There is limited experience with severely debilitated dogs or dogs with seriously compromised kidney or liver function. Please tell your veterinary surgeon if your dog has any of these.

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

Do not eat, drink or smoke while handling the veterinary medicinal product.
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 the eyes, they should be thoroughly flushed with plenty of water.
In case of accidental ingestion, especially in the case of children, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been investigated in pregnant dogs and lactating dogs. Use in pregnant dogs and lactating dogs during the first two weeks of lactation is therefore not recommended.

Interaction with other products and other forms of interaction:

Emodepside may interact with other veterinary medicinal products using the same transport system (e.g. macrocyclic lactones). The potential clinical consequences of such interactions have not been investigated.

Overdose (symptoms, emergency procedures, antidotes):

Slight and transient digestive tract disorders such as loose faeces and vomiting occurred occasionally when the veterinary medicinal product was administered at repeated doses of up to five times the recommended dose.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

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

Medicines should not be disposed of via wastewater. These measures should help to protect the environment. The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2023

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Procox oral suspension is supplied in two different pack sizes containing 7.5 or 20 ml. Not all pack sizes may be marketed.

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Approved 07 November 2023