

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

WORM STOP tablets for dogs

(in Czech Republic; Germany; Hungary; Portugal; Romania; Slovakia)

POPANDOG tablets for dogs

(in Spain)

TETRIAS PLUS tablets for dogs

(in Italy)

INPAR tablets for dogs

(in Poland)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains

Active substances:

Praziquantel 50 mg

Pyrantel embonate 144 mg

Fenbendazole 200 mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

Yellow or yellowish grey, round scored tablets.

4. CLINICAL PARTICULARS

4.1. Target species

Dogs

4.2. Indications for use, specifying the target species

For the treatment of mixed infections by both adult nematodes and cestodes in dogs of the following species:

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

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

Whipworms: *Trichuris vulpis* (adults)

Tapeworms: *Dipylidium caninum*, *Taenia hydatigena*, *Taenia pisiformis*. (adult and late immature forms)

4.3. Contraindications

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

Do not use simultaneously with any product containing piperazin derivatives and/or organic phosphate ester.

4.4. Special warning for each target species

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. In case of suspected lack of efficacy, it is necessary to ask veterinarian, who may recommends laboratory examination and based on results may advices/recommends product with different mechanism of action. In cases of confirmed mono-infections by cestodes or nematodes, a monovalent product containing a cestocide or a nematocide alone should be used.

Fleas serve as intermediate hosts and source of infection for one common type of tapeworm – *Dipylidium caninum*. Tapeworm infestation may reoccur unless control of intermediate hosts. such as fleas, mice as well as the environment is undertaken concurrently to the treatment.

4.5. Special precautions for use

Special precautions for use in animals

In order to decrease risk of reinvasion all animals kept together should be treated simultaneously.

It is recommended to dispose the excreted faeces, worms, segments and eggs and to clean and disinfect often the environment of the animals.

Pyrantel should be given with caution for dogs with cachexia.

Treatment of the debilitated or heavily infested animals (with visible parasites or segments in the faeces), should be performed by the veterinarian after risk/benefit evaluation connected with use of product. In such case veterinarian may recommends follow-up examination of faeces and retreatment with product of suitable spectrum of activity (i.e. in case of *Ancylostoma caninum* or *Toxocara canis* invasion – nematocide product).

Treatment of animals less than 6 weeks old may not be necessary.

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

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

People with known hypersensitivity to praziquantel, pyrantel embonate or fenbendazole should avoid contact with the veterinary medicinal product. Wash hands after use.

Special precautions should be taken during treatment - Children should not play with treated animals, dogs should not sleep with their owners, especially with children the days after treatment.

4.6. Adverse reactions (frequency and seriousness)

Rarely, a lack of appetite, diarrhoea, vomiting, and distress or, transitionally, a rise in the level of AST (aspartate aminotransferase) might occur.

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).

4.7. Use during pregnancy, lactation and lay

The safety of the veterinary medicinal product has not been established during the early pregnancy in dogs. Do not use in pregnant bitches during the first four weeks of gestation. After this time and during lactation use only according to the benefit risk assessment by the responsible veterinarian. In breeding dogs use only according to the benefit risk assessment by the responsible veterinarian.

4.8. Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.

Equally, do not administer together with organic phosphate esters and diethylcarbamazine. Due to similar mechanism of action and toxicological characteristics do not use this anthelmintic simultaneously with morantel and combinations of morantel.

4.9. Amounts to be administered and administration route

For oral treatment only.

Dosage:

The recommended dose is 1 tablet/10 kg bw (this is equivalent to 5 mg/kg praziquantel, 14,4 mg/kg pyrantel embonate and 20 mg/kg fenbendazole).

For routine treatment a single dose is sufficient.

In case of a diagnosed helminthiasis, the treatment should be repeated in 14 days. To ensure administration of a correct dose, body weight should be determined as accurately as possible.

Dog's bodyweight (kg)	Amount of tablets (piece)
<i>Puppies and small dogs</i>	
2-5	1/2
> 5-10	1
<i>Medium size dogs</i>	
>10-20	2
> 20-30	3
<i>Large dogs</i>	
>30-40	4

Method of administration:

The tablet can be given directly for oral administration or crushed, mixed into the feed. The animal does not need to be starved during the treatment.

Normally in adult dogs (above 6 months of age) deworming is performed every three months. If animal's owner will not decide to regular treatment with anthelmintics the possible alternative is faeces examination every 3 months. In some particular cases, i.e. lactating bitches, young dogs (below 6 months of age) or in shelters, deworming frequency may be higher. In such case consult your veterinarian in order to establish deworming protocol.

After prolonged administration of product it is recommended to consult veterinarian, who may recommend to change the product to minimize risk of parasite resistance occurrence.

4.10. Overdose symptoms, emergency procedures, antidotes), if necessary

In target animal tolerance studies, no clinical, haematological or biochemical parameters have changed significantly, even at doses in excess 5 times the recommended dose for 3 days.

Overdose of this medicinal product can occur very rarely under field conditions because of its wide therapeutic range.

If suspected toxic reactions do occur due to extreme overdose, the appropriate symptomatic treatment should be initiated if necessary.

4.11. Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: anthelmintic, praziquantel, combinations.

ATCvet code: QP52AA51

5.1 Pharmacodynamic properties

Mechanism of action

Pyrantel, a tetrahydropyrimidine derivative and its embonate salt, has been a well-known wide-spectrum anthelmintic against the parasites in dogs and other animals since 1966. Pyrantel depolarises neuromuscular synapses. It also blocks the choline esterase enzyme. These cell biological changes cause a paralysis of the worms, and thus their death. Pyrantel embonate component is effective against gastrointestinal roundworms and tapeworms.

Praziquantel, an isoquinolin derivative, is a highly effective anthelmintic against a wide range of tapeworms in adult and late immature forms in humans and animals alike. Praziquantel is very rapidly absorbed through the parasite's surface and distributed throughout the parasite. Praziquantel causes severe damage to the parasite integument, resulting in the contraction and paralysis of the parasites. There is an almost instantaneous tetanic contraction of the parasite musculature and a rapid vacuolization of

the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, especially calcium.

Fenbendazole, a methyl-5(feniltio)-2-benzimidazol carbamate, is a widely used benzimidazole compound (pharmacologically active metabolite of febantel). Mechanism of action is based on inhibition of polymerization of microtubules. Fenbendazole blocks the fumarate reductase enzyme in the worms, and blocks the glucose uptake, thus leading to damage of their energy-producing metabolic processes. Upon exhaustion of its energy reserves cause the paralysis of the worms, and thus their death.

It is suitable for a treatment against tapeworms, hookworms, whipworms, lungworms *Cysticercus tenuicollis* and *Giardia* infections.

Synergy of the combination of pyrantel embonate and fenbendazole ensures an increased effectivity against whipworms. Pyrantel embonate component alone ensures higher effectivity against the nematodes than fenbendazole, except whipworms, which proves the necessity of pyrantel embonate in the product.

Although fenbendazole is effective against *Taenia pisiformis* to some extent, the presence of praziquantel is still necessary in the combination in order to achieve 100% effectivity in the treatment against *T. pisiformis*, and *D. caninum*. There is evidence that fenbendazole has only a slight effect against *D. caninum* and *T. pisiformis*.

The product is a wide-range anthelmintic. It is effective against the following species: *Toxocara canis*, *Toxascaris leonina*, *Ancylostoma caninum*, *Uncinaria stenocephala*, *Trichuris vulpis*, *Dipylidium caninum*, *Taenia multiceps* and *Mesocestoides* species.

All ingredients of the product have an antiparasitic effect based on a different mechanism. This is particularly important because parasites might become resistant to certain anthelmintics after a while.

5.2 Pharmacokinetic particulars

Perorally administered praziquantel is absorbed almost completely from the intestinal tract. Maximum plasma concentration is obtained after 30-60 minutes in dogs. After absorption the drug is distributed to all organs; it passes the blood-brain barrier and also passes into the bile. Praziquantel is metabolized into inactive forms in the liver and secreted in bile. Inactive metabolites of praziquantel are excreted in the urine. The ubiquitous distribution is an asset in activity of praziquantel against cestodes larval or adult forms that have highly varied locations in the host. Praziquantel has rapid metabolism and excretion in dogs.

The embonate salt of pyrantel has low aqueous solubility, an attribute that reduces absorption from the gut and allows the drug to reach and be effective against parasites in the large intestine. Following absorption, pyrantel embonate is quickly and almost completely metabolized into inactive metabolites that are excreted rapidly in the urine and faeces. Maximum plasma concentration is obtained after 4-6 hours via oral administration in dogs.

Fenbendazole is a benzimidazole-compound and active metabolite of febantel. Fenbendazole and its known active sulphoxide metabolite in dogs appear in the liver and excreted via urine and faeces.

Maximum plasma concentration is realised between the first 1-2 hours after oral administration of the drug to dogs. 24-48 hours after this interval, the active ingredient cannot be identified at the plasma level.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Maize starch

Microcrystalline cellulose

Lactose monohydrate

Povidone

Sodium starch glycolate (Type A)

Talc

Magnesium stearate

Colloidal anhydrous silica

6.2. Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

Shelf-life after first opening the immediate packaging (polyethylene container): 3 months

Shelf-life after first opening the immediate packaging (blister): use immediately

6.4. Special precautions for storage

Store below 25 °C. Store in a dry place, protect from light.

Store in the original package. Keep out of sight and reach of children.

Any unused tablet fraction derived from blister should be discarded and not stored.

Half tablet packed in the polyethylene container should be stored in the original container.

6.5. Nature and composition of immediate packaging

Immediate packaging material: PVC/Alu blister or polyethylene container

Package size:

- carton box containing PVC/Alu blister of 1x2, 3x2, 1x10, 2x10, 10x10 and 20x10 tablets
- polyethylene container containing 200 tablets.

Not all pack sizes may be marketed.

6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. This veterinary medicinal should not enter watercourses, as this may be harmful for fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

Pharma World Pharmaceuticals Kft.

Szófia u. 18.

1068 Budapest

Hungary

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

Package Leaflet:

WORM STOP tablets for dogs
(in Czech Republic; Germany; Hungary; Portugal; Romania; Slovakia)

POPANDOG tablets for dogs
(in Spain)

TETRIAS PLUS tablets for dogs
(in Italy)

INPAR tablets for dogs
(in Poland)

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

Marketing authorisation holder :

Pharma World Pharmaceuticals Kft.

Szófia u. 18.

1068 BudapestHungary

(in Czech Republic; Germany; Hungary; Portugal; Romania; Spain; Slovakia)

SLAIS S.r.l.

Via Pacinotti, 33;05100 Terni (TR),

Italy

(in Italy)

Przedsiębiorstwo Wielobranżowe Vet-Agro Sp.z o.o.

ul. Gliniana 32; 20-616 Lublin,

Poland

(in Poland)

Manufacturer responsible for batch release:

Pernix Pharma Gyógyszergyártó Kft.

8900 Zalaegerszeg, Északi Iparterület,

Kamilla u. 3. (0788/58 Hrsz.)

Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

WORM STOP tablets for dogs

praziquantel, pyrantel embonate, fenbendazole

(in Czech Republic; Germany; Hungary; Portugal; Romania; Slovakia)

POPANDOG tablets for dogs
praziquantel, pyrantel embonate, fenbendazole
(in Spain)

TETRIAS PLUS tablets for dogs
praziquantel, pyrantel embonate, fenbendazole
(in Italy)

INPAR tablets for dogs
praziquantel, pyrantel embonate, fenbendazole
(in Poland)

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

One tablet contains

Active substances:

Praziquantel	50 mg
Pyrantel embonate	144 mg
Fenbendazole	200 mg

Yellow or yellowish grey, round scored tablets.

4. INDICATION

For the treatment of mixed infections by both adult nematodes and cestodes in dogs of the following species:

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

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

Whipworms: *Trichuris vulpis* (adults)

Tapeworms: *Dipylidium caninum, Taenia hydatigena, Taenia pisiformis*,. (adult and late immature forms)

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substances or to any of the excipients.
Do not use simultaneously with any product containing piperazin derivatives and/or organic phosphate ester.

6. ADVERSE REACTIONS

Rarely, a lack of appetite, diarrhoea, vomiting, and distress or, transitionally, a rise in the level of AST (aspartate aminotransferase) might occur.

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 effect, even those not already listed in the package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

For oral treatment only.

Dosage:

The recommended dose is 1 tablet/10 kg bw (this is equivalent to 5 mg/kg praziquantel, 14,4 mg/kg pyrantel embonate and 20 mg/kg fenbendazole For routine treatment a single dose is sufficient.

In case of a diagnosed helminthiasis, the treatment should be repeated in 14 days. To ensure administration of a correct dose, body weight should be determined as accurately as possible.

Dog's bodyweight (kg)	Amount of tablets (piece)
<i>Puppies and small dogs</i>	
2-5	1/2
> 5-10	1
<i>Medium size dogs</i>	
>10-20	2
>20-30	3
<i>Large dogs</i>	
>30-40	4

9. ADVICE ON CORRECT ADMINISTRATION

The tablet can be given directly for oral administration or crushed, mixed into the feed.

The animal not needs not be starved during the treatment.

Normally in adult dogs (above 6 months of age) deworming is performed every three months. If animal's owner will not decide to regular treatment with anthelmintics the possible alternative is faces examination every 3 months. In some particular cases, i.e. lactating bitches, young dogs (below 6 months of age) or in shelters, deworming frequency may be higher. In such case consult your veterinarian in order to establish deworming protocol.

After prolonged administration of product it is recommended to consult veterinarian, who may recommends to change the product to minimize risk of parasite resistance occurrence.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C. Store in a dry place, protect from light.

Store in the original package. Keep out of sight and reach of children.

Any unused tablet fraction derived from blister should be discarded and not stored.

Half tablet packed in the polyethylene container should be stored in the original container.

Do not use after expiry date indicated on the label after Exp.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

In case of suspected lack of efficacy, it is necessary to ask veterinarian, who may recommends laboratory examination and based on results may advices/recommends product with different mechanism of action. In cases of confirmed mono-infections by cestodes or nematodes, a monovalent product containing a cestocide or a nematocide alone should be used.

Fleas serve as intermediate hosts and source of infection for one common type of tapeworm – *Dipylidium caninum*. Tapeworm infestation may reoccur unless control of intermediate hosts, such as fleas, mice as well as the environment is undertaken concurrently to the treatment.

Special precautions for use in animals

In order to decrease risk of reinvasion all animals kept together should be treated simultaneously.

It is recommended to dispose the excreted faeces, worms, segments and eggs and to clean and disinfect often the environment of the animals.

Pyrantel should be given with caution for dogs with cachexia.

Treatment of the debilitated or heavily infested animals (with visible parasites or segments in the faeces), should be performed by the veterinarian after risk/benefit evaluation connected with use of product. In such case veterinarian may recommends follow-up examination of faeces and retreatment with product of suitable spectrum of activity (i.e. in case of *Ancylostoma caninum* or *Toxocara canis* invasion – nematocide product).

Treatment of animals less than 6 weeks old may not be necessary.

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

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

People with known hypersensitivity to praziquantel, pyrantel embonate or fenbendazole should avoid contact with the veterinary medicinal product. Wash hands after use.

Special precautions should be taken during treatment - children should not play with treated animals, dogs should not sleep with their owners, especially with children the days after treatment.

Use during pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during the early pregnancy in dogs. Do not use in pregnant bitches during the first four weeks of gestation. After this time and during lactation use only according to the benefit risk assessment by the responsible veterinarian. In breeding dogs use only according to the benefit risk assessment by the responsible veterinarian.

Interactions with other medicinal products and other forms of interactions:

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized. Equally, do not administer together with organic phosphate esters and diethylcarbamazine.

Due to similar mechanism of action and toxicological characteristics do not use this anthelmintic simultaneously with morantel and combinations of morantel.

Overdose symptoms, emergency procedures, antidotes:

No adverse effect was observed even at the 3-5 fold therapeutic dose, repeated 3 times.

Incompatibilities:

Not applicable

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 products should be disposed of in accordance with local requirements. This veterinary medicinal should not enter watercourses, as this may be harmful for fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

To be supplied only on veterinary prescription. – conditions and restrictions regarding supply and use should be completed nationally

For animal treatment only.

May be sold by authorized distributors only.

Packaging

Immediate packaging material: PVC/Alu blister or polyethylene container

Package size:

- carton box containing PVC/Alu blister of 1x2, 3x2, 1x10, 2x10, 10x10 and 20x10 tablets
- polyethylene container containing 200 tablets.

Not all pack sizes may be marketed.

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

WORM STOP tablets for dogs

(in Czech Republic; Germany; Hungary; Portugal; Romania; Slovakia)

POPANDOG tablets for dogs

(in Spain)

TETRIAS PLUS tablets for dogs

(in Italy)

INPAR tablets for dogs

(in Poland)

Praziquantel, pyrantel-embonate, fenbendazole

2. STATEMENT OF ACTIVE SUBSTANCES

One tablet contains:

Active substances: 50 mg praziquantel; 144 mg pyrantel-embonate; 200 mg fenbendazole.

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

2x tablets

6x tablets

10x tablets

20x tablets

100x tablets

200x tablets

5. TARGET SPECIES

Dogs

6. INDICATIONS

For OTC products

For the treatment of mixed infections by both adult nematodes and cestodes in dogs of the following species:

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

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

Whipworms: *Trichuris vulpis* (adults)

Tapeworms: *Dipylidium caninum*, *Taenia hydatigena*, *Taenia pisiformis*,. (adult and late immature forms)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral treatment only.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Exp: {mm/yyyy}

11. SPECIAL STORAGE CONDITIONS

Store below 25 °C. Store in a dry place, protected from light. Any unused tablet fractions derived from blister should be discarded and not stored.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. This veterinary medicinal should not enter watercourses, as this may be harmful for fish and other aquatic organisms.

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. – conditions and restrictions regarding supply and use should be completed nationally

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

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pharma World Pharmaceuticals Kft.

Szófia u. 18.

1068 Budapest, Hungary

(in Czech Republic; Germany; Hungary; Portugal; Romania; Spain; Slovakia)

SLAIS S.r.l.

Via Pacinotti, 33;05100 Terni (TR),

Italy

(in Italy)

Przedsiębiorstwo Wielobranżowe Vet-Agro Sp.z o.o.

ul. Gliniana 32; 20-616 Lublin,

Poland

(in Poland)

16. MARKETING AUTHORISATION NUMBER:

17. MANUFACTURER'S BATCH NUMBER

Batch number:

MINIMUM PARTICULARS TO APPEAR ON THE BLISTER

PVC/Alu blister foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

WORM STOP tabl.

(in Czech Republic; Germany; Hungary; Portugal; Romania; Slovakia)

POPANDOG tabl.

(in Spain)

TETRIAS PLUS tablets for dogs

(in Italy)

INPAR tablets for dogs

(in Poland)

praziquantelum, pyranteli embonas, fenbendazolum

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Pharma World Pharmaceuticals Kft.

(in Czech Republic; Germany; Hungary; Portugal; Romania; Spain; Slovakia)

SLAIS S.r.l.

(in Italy)

Przedsiębiorstwo Wielobranżowe Vet-Agro Sp.z o.o.

(in Poland)

3. EXPIRY DATE

Exp: {mm/yyyy}

4. BATCH NUMBER

Lot.:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Kizárólag állatgyógyászati alkalmazásra.

Für Tiere.

Pouze pro zvířata.

Wyłącznie dla zwierząt.

Uso veterinário.

Uso veterinario.

Len pre zvieratá.

Numai pentru uz veterinar.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

polyethylene container

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release , if different

Marketing authorisation holder :

Pharma World Pharmaceuticals Kft.

Szófia u. 18.

1068 BudapestHungary

(in Czech Republic; Germany; Hungary; Portugal; Romania; Spain; Slovakia)

SLAIS S.r.l.

Via Pacinotti, 33;05100 Terni (TR),

Italy

(in Italy)

Przedsiębiorstwo Wielobranżowe Vet-Agro Sp.z o.o.

ul. Gliniana 32; 20-616 Lublin,

Poland

(in Poland)

Manufacturer responsible for batch release:

Pernix Pharma Gyógyszergyártó Kft.

8900 Zalaegerszeg, Északi Iparterület,

Kamilla u. 3. (0788/58 Hrsz.)

Hungary

2. Name of the veterinary medicinal product

WORM STOP tablets for dogs

praziquantel, pyrantel embonate, fenbendazole

(in Czech Republic; Germany; Hungary; Portugal; Romania; Slovakia)

POPANDOG tablets for dogs

praziquantel, pyrantel embonate, fenbendazole

(in Spain)

TETRIAS PLUS tablets for dogs

praziquantel, pyrantel embonate, fenbendazole

(in Italy)

INPAR tablets for dogs

praziquantel, pyrantel embonate, fenbendazole
(in Poland)

3. Statement of the active substance (s) and other ingredients

One tablet contains

Active substances:

Praziquantel 50 mg
Pyrantel embonate 144 mg
Fenbendazole 200 mg

200 yellow or yellowish grey, round scored tablets

4. Pharmaceutical form

Tablet

5. Package size

200x tablets

6. INDICATION(S)

For the treatment of mixed infections by both adult nematodes and cestodes in dogs of the following species:

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

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

Whipworms: *Trichuris vulpis* (adults)

Tapeworms: *Dipylidium caninum*, *Taenia hydatigena*, *Taenia pisiformis*, (adult and late immature forms)

7. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substances or to any of the excipients. Do not use simultaneously with any product containing piperazin derivatives and/or organic phosphate ester.

8. ADVERSE REACTIONS

Rarely, a lack of appetite, diarrhoea, vomiting, and distress or, transitionally, a rise in the level of AST (aspartate aminotransferase) might occur.

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 effect, even those not already listed in the package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

9. Target species

Dogs

10. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

For oral treatment only.

Dosage:

The recommended dose is 1 tablet/10 kg bw (this is equivalent to 5 mg/kg praziquantel, 14,4 mg/kg pyrantel embonate and 20 mg/kg fenbendazole).

For routine treatment a single dose is sufficient. In case of a diagnosed helminthiasis, the treatment should be repeated in 14 days. To ensure administration of a correct dose, body weight should be determined as accurately as possible.

Dog's bodyweight (kg)	Amount of tablets (piece)
<i>Puppies and small dogs</i>	
2-5	1/2
> 5-10	1
<i>Medium size dogs</i>	
> 10-20	2
> 20-30	3
<i>Large dogs</i>	
> 30-40	4

11. ADVICE ON CORRECT ADMINISTRATION

The tablet can be given directly for oral administration or crushed, mixed into the feed.

The animal need not be starved during the treatment.

Normally in adult dogs (above 6 months of age) deworming is performed every three months. If animal's owner will not decide to regular treatment with anthelmintics the possible alternative is feces examination every 3 months. In some particular cases, i.e. lactating bitches, young dogs (below 6 months of age) or in shelters, deworming frequency may be higher. In such case consult your veterinarian in order to establish deworming protocol.

After prolonged administration of product it is recommended to consult veterinarian, who may recommends to change the product to minimize risk of parasite resistance occurrence.

12. Withdrawal period(s)

Not applicable.

13. Special storage precautions

Store below 25 °C. Store in a dry place, protect from light.

Half tablet packed in the polyethylene container should be stored in the original container.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

14. SPECIAL WARNING(S)

Special warning for each target species:

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

In case of suspected lack of efficacy, it is necessary to ask veterinarian, who may recommends laboratory examination and based on results may advices/recommends product with different mechanism of action In cases of confirmed mono-infections by cestodes or nematodes, a monovalent product containing a cestocide or a nematocide alone should be used.

Fleas serve as intermediate hosts and source of infection for one common type of tapeworm – *Dipylidium caninum*. Tapeworm infestation may reoccur unless control of intermediate hosts, such as fleas, mice as well as the environment is undertaken concurrently to the treatment.

Special precautions for use in animals

In order to decrease risk of reinvasion all animals kept together should be treated simultaneously.

It is recommended to dispose the excreted faeces, worms, segments and eggs and to clean and disinfect often the environment of the animals.

Pyrantel should be given with caution for dogs with cachexia.

Treatment of the debilitated or heavily infested animals (with visible parasites or segments in the faeces), should be performed by the veterinarian after risk/benefit evaluation connected with use of product. In such case veterinarian may recommends follow-up examination of faeces and retreatment with product of suitable spectrum of activity (i.e. in case of *Ancylostoma caninum* or *Toxocara canis* invasion – nematocide product).

Treatment of animals less than 6 weeks old may not be necessary.

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

In case of accidental ingestion, seek medical advics immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to praziquantel, pyrantel embonate or fenbendazole should avoid contact with the veterinary medicinal product. Wash hands after use.

Special precautions should be taken during treatment - children should not play with treated animals, dogs should not sleep with their owners, especially with children the days after treatment.

Use during pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during the early pregnancy in dogs. Do not use in pregnant bitches during the first four weeks of gestation. After this time and during lactation use only according to the benefit risk assessment by the responsible veterinarian. In breeding dogs use only according to the benefit risk assessment by the responsible veterinarian.

Interactions with other medicinal products and other forms of interactions:

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized. Equally, do not administer together with organic phosphate esters and diethylcarbamazine.

Due to similar mechanism of action and toxicological characteristics do not use this anthelmintic simultaneously with morantel and combinations of morantel.

Overdose symptoms, emergency procedures, antidotes:

No adverse effect was observed even at the 3-5 fold therapeutic dose, repeated 3 times.

Incompatibilities:

Not applicable

15. 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 products should be disposed of in accordance with local requirements. This veterinary medicinal should not enter watercourses, as this may be harmful for fish and other aquatic organisms.

16. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

17. OTHER INFORMATION

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

May be sold by authorized distributors only.

Packaging

Immediate packaging material: PVC/Alu blister or polyethylene container

Package size:

- carton box containing PVC/Alu blister of 1x2, 3x2, 1x10, 2x10, 10x10 and 20x10 tablets
- polyethylene container containing 200 tablets.

Not all pack sizes may be marketed.

18. 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. – conditions and restrictions regarding supply and use should be completed nationally

19. The words “Keep out of the sight and reach of children”

Keep out of sight and reach of children.

20. Expiry date

Exp:

Shelf-life after first opening the immediate packaging (polyethylene container): 3 months.

21. Marketing authorisation number(s)

22. Manufacturer’s batch number

Batch/Lot :