1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Wormaway Plus XL Tablets for Dogs (IE)
Prazical XL Tablets for Dogs (FR)
CESTAGUARD Plus XL, Tablets for Large Dogs (RO)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Praziquantel	175 mg
Pyrantel Embonate	504 mg (equivalent to 175 mg pyrantel)
Febantel	525 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Microcrystalline cellulose
Magnesium stearate
Colloidal anhydrous silica
Croscarmellose sodium
Sodium lauryl sulfate
Pork flavour

A yellow coloured oblong tablet with a breakline on both sides.
The tablets can be divided into two equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Treatment of mixed infections by nematodes and cestodes of the following species

Nematodes:

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

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

Whipworms: *Trichuris vulpis* (adults).

Cestodes:

Tapeworms: *Echinococcus* species *(E. granulosus, E. multilocularis), Taenia* species *(T. hydatigena, T. pisiformis, T. taeniformis), Dipylidium caninum* (adult and immature forms).

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use during the 1st and 2nd trimester of pregnancy (see section 3.7)

3.4 Special warnings

Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum*.
Tapeworm infestation is certain to reoccur unless control of intermediate hosts such as fleas, mice, etc. is undertaken.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
To minimise the risk of reinfestation and new infestation, excreta should be collected and properly disposed of for 24 hours following treatment.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not Applicable.

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

Special precautions for the protection of the environment:
Not applicable.

Other precautions:
The veterinary medicinal product is effective against *Echinococcus* spp. which does not occur in all EU member states but are becoming more common in some. Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (WOAH), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (diarrhoea, emesis)

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and Lactation:

Teratogenic effects attributed to high doses of febantel administered during early pregnancy have been reported in rats, sheep and dogs.

The safety of the veterinary medicinal product has not been investigated during the 1st and 2nd trimester of pregnancy. Do not use in pregnant dogs during the 1st and 2nd trimester of pregnancy (see section 3.3).

A single treatment during the last trimester of pregnancy or during lactation has been demonstrated safe.

3.8 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 antagonised.

Concurrent use with other cholinergic compounds can lead to toxicity.

3.9 Administration routes and dosage

Oral use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Dosage:

For treatment of dogs, 1 tablet per 35 kg body weight (15 mg febantel, 14.4 mg pyrantel embonate and 5 mg praziquantel/kg body weight).

Dosages are as follows:

Bodyweight (kg)	**Tablets**
Approximately 17.5 kg.	½ Wormaway Plus XL tablet
31-35 kg.	1 Wormaway Plus XL tablet
>35-40 kg.	1 Wormaway XL tablet plus ½ Wormaway Plus tablet
>40-45 kg.	1 Wormaway Plus XL tablet plus 1 Wormaway Plus tablet

>45-50 kg.	1 Wormaway Plus XL tablet plus 1½ Wormaway Plus tablets
>50-55 kg.	1 Wormaway Plus XL tablet plus 2 Wormaway Plus tablets
>55-60 kg.	1 Wormaway Plus XL tablet plus 2½ Wormaway Plus tablets
>60-65 kg.	1 Wormaway Plus XL tablet plus 3 Wormaway Plus tablets
>65-70 kg.	2 Wormaway Plus XL tablets

The tablets can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.

Tablets should be given as a single administration.

Part tablets should be discarded immediately or returned to the open blister until used.

If there is a risk for re-infestation, the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In safety studies, a single dose of 5 times the recommended dose of the combination of praziquantel, pyrantel embonate or greater gave rise to occasional vomiting.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QP52AA51

4.2 Pharmacodynamics

This veterinary medicinal product contains anthelmintics active against gastrointestinal roundworms and tapeworms. The veterinary medicinal product contains three active substances, as follows:

1. Febantel, a probenzimidazole

2. Pyrantel embonate (pamoate), a tetrahydropyrimidine derivative

3. Praziquantel, a partially hydrogenated pyrazinoisoquinoline derivative

In this fixed combination, pyrantel and febantel act against all relevant nematodes (ascarids, hookworms, and whipworms) in dogs. In particular, the activity spectrum covers *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum* and *Trichuris vulpis*.

This combination shows synergistic activity in the case of hookworms and febantel is effective against *T. vulpis*.
The spectrum of activity of praziquantel covers all important cestode species in dogs, in particular *Taenia* spp., *Dipylidium caninum, Echinococcus granulosus* and *Echinococcus multilocularis*. Praziquantel acts against all adult and immature forms of these parasites.

Praziquantel is very rapidly absorbed through the parasite's surface and distributed throughout the parasite. Both in vitro and in vivo studies have shown that 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 vacuolisation of the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, especially calcium.
Pyrantel acts as a cholinergic agonist. Its mode of action is to stimulate nicotinic cholinergic receptors of the parasite, induce spastic paralysis of the nematodes and thereby allow removal from the gastrointestinal system by peristalsis.
Within the mammalian system, febantel undergoes ring closure, forming fenbendazole and oxfendazole. It is these chemical entities which exert the anthelmintic effect by inhibition of tubulin polymerisation. Formation of microtubules is thereby prevented, resulting in disruption of structures vital to the normal functioning of the helminth. Glucose uptake in particular is affected, leading to a depletion in cell ATP. The parasite dies upon exhaustion of its energy reserves, which occurs 2 – 3 days later.

4.3 Pharmacokinetics

Perorally administered praziquantel is absorbed almost completely from the intestinal tract. After absorption, the drug is distributed to all organs. Praziquantel is metabolised into inactive forms in the liver and secreted in bile. It is excreted within 24 hours to more than 95% of the administered dosage. Only traces of non-metabolised praziquantel are excreted.
Following administration of the veterinary medicinal product to dogs, peak plasma concentrations of praziquantel were achieved by approximately 2.5 hours.

The pamoate 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 pamoate is quickly and almost completely metabolized into inactive metabolites that are excreted rapidly in the urine.
Febantel is absorbed relatively rapidly and metabolised to a number of metabolites including fenbendazole and oxfendazole, which have anthelmintic activity.

Following administration of the veterinary medicinal product to dogs, peak plasma concentrations of fenbendazole and oxfendazole were achieved by approximately 7-9 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years
Shelf life of half tablets: 14 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions
Each time an unused half tablet is stored, it should be returned to the open blister space and inserted back into the outer carton.
Keep the blister in the outer carton.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is presented in:
Blister packs made up of PVC/PE/PCTFE with 20µ hard tempered aluminium foil with 2, 4, 5, 6, 8, 10, 12, 14, 16, 18 or 20 tablets per blister.
The Blisters are packed into cartons containing either 2, 4, 5, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 64, 68, 70, 72, 76, 80, 84, 88, 92, 96, 98, 100, 104, 106, 108, 112, 116, 120, 140, 150, 180, 200, 204, 206, 208, 250, 280, 300, 500 or 1000 tablets.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited,

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

IE, RO: Veterinary medicinal product not subject to prescription.

FR: Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON FOR PACK SIZES OF 2,4, 5, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42 ,44, 48 TABLETS, AND UPWARDS }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Wormaway Plus XL Tablets (IE)
Prazical XL Tablets (FR)
CESTAGUARD Plus XL, Tablets (RO)

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains: 175 mg Praziquantel, 504 mg Pyrantel Embonate (equivalent to 175 mg pyrantel) and 525 mg Febantel.

3. PACKAGE SIZE

2, 4, 5, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 64, 68, 70, 72, 76, 80, 84, 88, 92, 96, 98, 100, 104, 106, 108, 112, 116, 120, 140, 150, 180, 200, 204, 206, 208, 250, 280, 300, 500 or 1000 tablets.

4. TARGET SPECIES

Dogs.

5. INDICATIONS

For products not subject to veterinary prescription.

Treatment of mixed infections by nematodes and cestodes.

6. ROUTES OF ADMINISTRATION

Oral use.
1 tablet per 35 kg bodyweight.
The tablets can be given directly to the dog or disguised in food.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Unused half tablet must be used within 14 days.

9. SPECIAL STORAGE PRECAUTIONS

Each time an unused half tablet is stored, it should be returned to the open blister space and inserted back into the outer carton.
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

Chanelle Pharmaceuticals Manufacturing Ltd.,

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

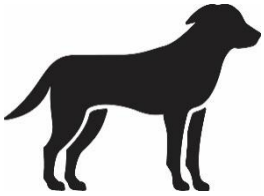
{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Wormaway Plus XL (IE)

Prazical XL (FR)

CESTAGUARD Plus XL (RO)



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each tablet contains 175 mg Praziquantel, 504 mg Pyrantel Embonate (equivalent to 175 mg Pyrantel) and 525 mg Febantel.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Wormaway Plus XL Tablets for Dogs (IE)
Prazical XL Tablets for Dogs (FR)
CESTAGUARD Plus XL, Tablets for Large Dogs (RO)

2. Composition

Each tablet contains 175 mg Praziquantel, 504 mg Pyrantel Embonate (equivalent to 175 mg pyrantel) and 525 mg Febantel.
A yellow coloured oblong tablet with a breakline on both sides.
The tablets can be divided into two equal parts.

3. Target species

Dogs.

4. Indications for use

Treatment of mixed infections by nematodes and cestodes of the following species

Nematodes:
Ascarids: *Toxocara canis, Toxascaris leonina* (adult and late immature forms).
Hookworms: *Uncinaria stenocephala, Ancylostoma caninum* (adults).
Whipworms: *Trichuris vulpis* (adults).

Cestodes:
Tapeworms: *Echinococcus species (E. granulosus, E. multilocularis), Taenia species (T. hydatigena, T. pisiformis, T. taeniformis), Dipylidium caninum* (adult and immature forms).

5. Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use during the 1st and 2nd trimester of pregnancy (see section Special warnings – Pregnancy and lactation).

6. Special warnings

Special warnings:

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.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
To minimise the risk of reinfestation and new infestation, excreta should be collected and properly disposed of for 24 hours following treatment.

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

Other precautions:

The veterinary medicinal product is effective against *Echinococcus* spp. which does not occur in all EU member states but are becoming more common in some. Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (WOAH), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

Pregnancy and lactation:

Teratogenic effects attributed to high doses of febantel administered during early pregnancy have been reported in rats, sheep and dogs.
The safety of the veterinary medicinal product has not been investigated during the 1st and 2nd trimester of pregnancy. Do not use in pregnant dogs during the 1st and 2nd trimester of pregnancy (see section Contraindications).
A single treatment during the last trimester of pregnancy or during lactation has been demonstrated safe.

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.
Concurrent use with other cholinergic compounds can lead to toxicity.

Overdose:

In safety studies, a single dose of 5 times the recommended dose of the combination of praziquantel, pyrantel embonate or greater gave rise to occasional vomiting.

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Digestive tract disorders (diarrhoea, emesis)

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:

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

Oral use.

The recommended dose rates are:
1 tablet per 35 kg body weight (15 mg febantel, 14.4 mg pyrantel embonate and 5 mg praziquantel/kg body weight).

Dosage table:

Bodyweight (kg)	**Tablets**
Approx 17.5 kg.	½ Wormaway Plus XL tablet
31-35 kg.	1 Wormaway Plus XL tablet
>35-40 kg.	1 Wormaway Plus XL tablet plus ½ Wormaway Plus tablet
>40-45 kg.	1 Wormaway Plus XL tablet plus 1 Wormaway Plus tablet
>45-50 kg.	1 Wormaway Plus XL tablet plus 1½ Wormaway Plus tablets
>50-55 kg.	1 Wormaway Plus XL tablet plus 2 Wormaway Plus tablets
>55-60 kg.	1 WormawayPlus XL tablet plus 2½ Wormaway Plus tablets
>60-65 kg.	1 Wormaway Plus XL tablet plus 3 Wormaway Plus tablets
>65-70 kg.	2 Wormaway Plus XL tablets

The tablets can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.
Tablets should be given as a single administration.
If there is a risk for re-infestation, the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration.
Part tablets should be discarded immediately or returned to the open blister until used.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature 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.
Shelf life of half tablets: 14 days.
Each time an unused half tablet is stored, it should be returned to the open blister space and inserted back into the outer carton.
Keep the blister in the outer carton.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
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

IE, RO: Veterinary medicinal product not subject to prescription.
FR: Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Blister packs made up of PVC/PE/PCTFE with 20µ hard tempered aluminium foil with 2, 4, 5, 6, 8, 10, 12, 14, 16, 18 or 20 tablets per blister.
The Blisters are packed into cartons containing either 2, 4, 5, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 64, 68, 70, 72, 76, 80, 84, 88, 92, 96, 98, 100, 104, 106, 108, 112, 116, 120, 140, 150, 180, 200, 204, 206, 208, 250, 280, 300, 500 or 1000 tablets.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Chanelle Pharmaceuticals Manufacturing Limited.
Loughrea,
Co. Galway,
Ireland.

Telephone: +353 (0)91 841788
vetpharmacoviggroup@chanellegroup.ie

Local representatives and contact details to report suspected adverse reactions:

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