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

Quantilex Plus XL Tablets

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 NUMBER

Vm 08749/3016

15. BATCH NUMBER

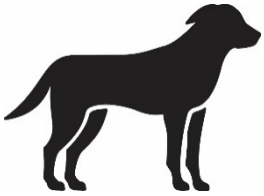
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quantilex Plus XL



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

Quantilex Plus XL tablets For Dogs

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**
Approximately 17.5 kg.	½ Strantel/Exitel/Quantilex Plus XL tablet
31-35 kg.	1 Strantel/Exitel/Quantilex Plus XL tablet
>35-40 kg.	1 Strantel/Exitel Plus/Quantilex XL tablet plus ½ Strantel/Exitel/Quantilex Plus tablet
>40-45 kg.	1 Strantel/Exitel/Quantilex Plus XL tablet plus 1 Strantel/Exitel/Quantilex Plus tablet
>45-50 kg.	1 Strantel/Exitel/Quantilex Plus XL tablet plus 1½ Strantel/Exitel/Quantilex Plus tablets
>50-55 kg.	1 Strantel/Exitel/Quantilex Plus XL tablet plus 2 Strantel/Exitel/Quantilex Plus tablets
>55-60 kg.	1 Strantel/Exitel/Quantilex Plus XL tablet plus 2½ Strantel/Exitel/Quantilex Plus tablets
>60-65 kg.	1 Strantel/Exitel/Quantilex Plus XL tablet plus 3 Strantel /Exitel/Quantilex Plus tablets
>65-70 kg.	2 Strantel/Exitel/Quantilex 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

CZ, IE, NL, SK, UK: Veterinary medicinal product not subject to prescription.

FR, PT: Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 08749/3016

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

September 2023

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.

Approved 04 December 2023