PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quantilex Duo 12.5 mg/125 mg Flavoured Tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active substances:
Milbemycin oxime 12.5 mg
Praziquantel 125.0 mg

3. PACKAGE SIZE

2, 4, 8, 10, 20, 30, 50, 100, 200 or 500 tablets.

4. TARGET SPECIES

Dogs.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

N/A.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Keep the blister in the outer carton in order to protect from light.
Any unused half tablets should be returned to the open blister and discarded after 4 weeks.

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

Vm 08749/5130
Vm 08749/3093

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {BLISTER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quantilex Duo

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each tablet contains:
Milbemycin oxime 12.5 mg/tablet
Praziquantel 125.0 mg/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quantilex Duo 12.5 mg/125 mg Flavoured Tablets for Dogs (Milbemycin / Praziquantel)

2. COMPOSITION

Each tablet contains:

Active substances:
Milbemycin oxime 12.5 mg
Praziquantel 125.0 mg

3. TARGET SPECIES

Dogs.

4. INDICATIONS FOR USE

In dogs: treatment of mixed infections by gastrointestinal roundworms, tapeworms, hookworms and whipworms and also for the treatment and prevention of the lungworm *Angiostroglyus vasorum* and prevention of the heartworm *Dirofilaria immitis*, where concomitant tapeworm treatment is indicated.

5. CONTRAINDICATIONS

Do not use in dogs weighing less than 5 kg.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
See also section 6 “Special warnings” point "Special precautions for use".

6. SPECIAL WARNINGS

Special warnings:
Studies with milbemycin oxime indicate that the margin of safety in certain dogs of Collie or related breeds is less than in other breeds. In these dogs, the recommended dose should be strictly observed.
The tolerance of the veterinary medicinal product in young puppies from these breeds has not been investigated.
Clinical signs in Collies are similar to those seen in the general dog population when overdosed (see section 12).

Special precautions for safe use in the target species:
As per good veterinary practice, animals should be weighed to ensure accurate dosing.

Treatment of dogs with a high number of developing Heartworm in their blood circulation (microfilaremia) can sometimes lead to the appearance of hypersensitivity reactions that are associated with the release of proteins from dead or dying developing Heartworm and are not a direct toxic effect of the veterinary medicinal product. The use in dogs suffering from microfilaremia is thus not recommended. A veterinary consultation is advised to exclude the presence of any concurrent infestation of Heartworm. In the case of a positive diagnosis, therapy that treats only adult Heartworms is indicated before administering the veterinary medicinal product.

No studies have been performed with severely debilitated dogs or individuals with seriously compromised kidney or liver function. the veterinary medicinal product is not recommended for such animals or only according to a benefit/risk assessment by the responsible veterinarian.

In dogs less than 4 weeks old, tape worm infection is unusual. Treatment of animals less than 4 weeks old with a combination product may therefore not be necessary.

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

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.
In the event of accidental ingestion of the tablets, particularly by a child, seek medical advice immediately and show the package leaflet or the label to the doctor.

Other precautions:
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 (e.g. experts or institutes of parasitology).

Pregnancy and lactation:
The veterinary medicinal product may be used in breeding dogs including pregnant and lactating bitches.

Interaction with other medicinal products and other forms of interaction:
Although the concurrent use of the veterinary medicinal product with selamectin is well tolerated, in the absence of further studies, caution should be taken in the case of concurrent use of the veterinary medicinal product and other macrocyclic lactones.

Overdose:
No other signs than those observed at the recommended dose have been observed (see section 6 ‘Special warnings’).

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
Not applicable.

7. ADVERSE EVENTS

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (such as Diarrhoea, Drooling, Emesis) Hypersensitivity reaction Neurological disorders (such as Ataxia, Convulsions, Muscle tremors) Systemic disorders (such as Anorexia, Lethargy)

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, the local representative of the marketing authorisation holder using the contact details at the end of this leaflet , or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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

Oral use.
Underdosing could result in ineffective use and may favour resistance development.
To ensure a correct dosage, body weight should be determined as accurately as possible.
Minimum recommended dose rate: 0.5 mg milbemycin oxime and 5 mg praziquantel per kg are given as a single dose. The veterinary medicinal product should be administered with or after some food.

Depending on the bodyweight of the dog, the practical dosing is as follows:

Weight	No of tablets
> 5-25 kg	1 tablet
> 25 - 50 kg	2 tablets
> 50 - 75 kg	3 tablets

In cases when heartworm disease prevention is used and at the same time treatment against tapeworm is required, the veterinary medicinal product can replace the monovalent product for the prevention of heartworm disease.

For treatment of *Angiostrongylus vasorum* infections, milbemycin oxime should be given four times at weekly intervals. It is recommended, where concomitant treatment against cestodes is indicated, to treat once with the veterinary medicinal product and continue with the monovalent product containing milbemycin oxime alone, for the remaining three weekly treatments.

In endemic areas administration of the veterinary medicinal product every four weeks will prevent angiostrongylosis by reducing immature adult (L5) and adult parasite burden, where concomitant treatment against cestodes is indicated.

For the treatment of *Thelazia callipaeda*, milbemycin oxime should be given in 2 treatments, seven days apart. Where concomitant treatment against cestodes is indicated, the veterinary medicinal product can replace the monovalent product containing milbemycin oxime alone.

9. ADVICE ON CORRECT ADMINISTRATION

The veterinary medicinal product is given by oral administration with or after some food.

10. WITHDRAWAL PERIODS

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children.
Do not store above 25 °C.
Keep the blister in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after Exp. The expiry date refers to the last day of that month.
Any unused half tablets should be returned to the open blister and discarded after 4 weeks.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater. The veterinary medicinal product should not enter water courses as it may be dangerous for fish and other aquatic organisms. 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. 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

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 08749/5130
Vm 08749/3093

Pack sizes: 2, 4, 8, 10, 20, 30, 50, 100, 200 or 500 tablets.

Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
H62 FH90
Ireland

Manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland

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

17. OTHER INFORMATION

POM-V Veterinary medicinal product subject to prescription.

For animal treatment only.

Gavin Hall
Approved: 21 October 2025