PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Wormax Plus 12.5/125 mg chewable tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each chewable tablet contains:

Active substances:
Milbemycin oxime 12.5 mg
Praziquantel 125.0 mg

3. PACKAGE SIZE

2 chewable tablets
4 chewable tablets
8 chewable tablets
10 chewable tablets
16 chewable tablets
20 chewable tablets
24 chewable tablets
30 chewable tablets
32 chewable tablets
40 chewable tablets
48 chewable tablets
50 chewable tablets
96 chewable tablets
100 chewable tablets
192 chewable tablets
200 chewable tablets
480 chewable tablets
500 chewable tablets

4. TARGET SPECIES

Dogs (≥ 5 kg)

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

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

C&H Generics Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 40162/3013 (NI)
Vm 40162/5013 (GB)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {BLISTER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Wormax Plus

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}
Once opened, use immediately.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Wormax Plus 12.5/125 mg chewable tablets for dogs

2. COMPOSITION

Each chewable tablet contains:

Active substances:

Milbemycin oxime	12.5 mg
Praziquantel	125.0 mg

Excipients:

Glycerol (E 422)	460.6 mg
Propylene glycol (E 1520)	4.54 mg
Iron oxide, brown (E 172)	3.29 mg
Butylhydroxyanisole (E 320)	1.32 mg
Propyl gallate (E 310)	0.46 mg

Oval shaped, dark brown chewable tablet.

3. TARGET SPECIES

Dogs (≥ 5 kg)

4. INDICATIONS FOR USE

For dogs with, or at risk from mixed infections of cestodes, gastrointestinal nematodes, eyeworm, lungworms and/or heartworm. This veterinary medicinal product is only indicated when use against cestodes and nematodes or prevention of heartworm disease/angiostrongylosis is indicated at the same time.

Cestodes:
Treatment of tapeworms: *Dipylidium caninum, Taenia* spp*., Echinococcus* spp*., Mesocestoides* spp*.*

Gastrointestinal Nematodes:
Treatment of:
Hookworm: *Ancylostoma caninum*
Roundworms: *Toxocara canis, Toxascaris leonina*
Whipworm: *Trichuris vulpis*

Eyeworm
Treatment of *Thelazia callipaeda* (see specific treatment schedule under section 8 “Dosage for each species, routes and method of administration”).

Lungworms
Treatment of:
Angiostrongylus vasorum (Reduction of the level of infection by immature adult (L5) and adult parasite stages; see specific treatment and prevention disease schedules under section 8 “Dosage for each species, routes and method of administration”).

Crenosoma vulpis (Reduction of the level of infection).

Heartworm
Prevention of heartworm disease (*Dirofilaria immitis*) if concomitant treatment against cestodes 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

6. SPECIAL WARNINGS

Special warnings:
The possibility that other animals in the same household can be a source of re-infection should be considered, and these should be treated as necessary with an appropriate veterinary medicinal product.
It is recommended to treat all the animals living in the same household concomitantly.
When infection with the cestode *D. caninum* has been confirmed, concomitant treatment against intermediate hosts, such as fleas and lice, should be discussed with a veterinarian to prevent re-infection.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
Unnecessary use of antiparasitics or use deviating from the instructions given in the package leaflet may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual animal.

The use of the veterinary medicinal product should follow the implementation of appropriate diagnostic measures towards mixed infections by nematodes and cestodes with consideration of animal history and characteristics (e.g. age, health status), environment (e.g. kennelled dogs, hunting dogs), feeding (e.g. access to raw meat), geographical location and travel. Judgement of the administration of the veterinary medicinal product in dogs at risk from mixed re-infections or in specific at risk situations (such as zoonotic risks), should be made by the responsible veterinarian.

In the absence of risk of co-infection with nematodes or cestodes, a narrow spectrum veterinary medicinal product should be used.

Resistance of *Dipylidium caninum* to praziquantel as well as cases of multi-drug resistance of *Ancylostoma caninum* to milbemycin oxime and resistance of *Dirofilaria immitis* to macrocyclic lactones have been reported.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method. Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.

Special precautions for safe use in the target species:
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 “Overdose”).
Treatment of dogs with a high number of circulating microfilariae can sometimes lead to the appearance of hypersensitivity reactions, such as pale mucous membranes, vomiting, trembling, laboured breathing or excessive salivation. These reactions are associated with the release of proteins from dead or dying microfilariae and are not a direct toxic effect of the veterinary medicinal product. The use in dogs suffering from microfilaremia is thus not recommended.
In heartworm risk-areas, or in the case it is known that a dog has been travelling to and from heartworm risk regions, before using the veterinary medicinal product, a veterinary consultation is advised to exclude the presence of any concurrent infestation of *Dirofilaria immitis*. In the case of a positive diagnosis, adulticidal therapy 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 veterinary medicinal product may therefore not be necessary.
As the tablets are flavoured, they should be stored in a safe place out of the reach of animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may be harmful when ingested, particularly for children. To avoid accidental ingestion, the veterinary medicinal product should be stored out of sight and reach of children.
In case of accidental ingestion of the tablets, particularly by a child, seek medical advice immediately and show the package leaflet or the label to the physician.
This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to the active substances or to the excipients, butylhydroxyanisole (E320) and propyl gallate (E310), should avoid contact with the

veterinary medicinal product. If contact occurs, wash hands and seek medical advice in case of hypersensitivity reactions.
Wash hands after use.

Special precautions for the protection of the environment:
See section 12

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 safety of the veterinary medicinal product has been established during pregnancy and lactation.
Can be used in pregnant and lactating bitches.

Fertility:
Can be used in breeding animals

Interaction with other medicinal products and other forms of interaction:
No interactions were observed when the recommended dose of the macrocyclic lactone selamectin was administered during treatment with an equivalent product of comparable composition at the recommended dose.
Although not recommended, the concomitant use of an equivalent product of comparable composition with a spot on containing moxidectin and imidacloprid at recommended dose rates following a single application was well tolerated in one experimental study in beagle dogs at the age 11 months or older. Transient neurological adverse reactions (poor proprioception, flaccid frontal and hind legs, incoordination, slight tremors and high stepping gait of the hind limbs only) were observed after concurrent administration of both products in another study conducted in puppies aged 8-12 weeks. Such signs were however not observed in this study after giving the equivalent product of comparable composition alone.
The safety and efficacy of this combination have not been investigated in field studies.
In the absence of further studies, caution should be taken in the case of concurrent use with any other macrocyclic lactone. Also, no such studies have been performed with breeding animals, Collies, related breeds and their crosses.

Overdose:
The adverse reactions observed are the same as those observed at the recommended dose (see section 7 “Adverse events”) but more pronounced.

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 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 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 chewable tablet
> 25 - 50 kg	2 chewable tablets
> 50 - 75 kg	3 chewable tablets

In cases when heartworm disease prevention is used and at the same time treatment against tapeworm is required, the 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 product and continue with the monovalent product containing milbemycin oxime alone, for the remaining three weekly treatments.

In endemic areas administration of the 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 product can replace the monovalent product containing milbemycin oxime alone.

9. ADVICE ON CORRECT ADMINISTRATION

The 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.
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.
Shelf life after first opening the immediate packaging: use immediately

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 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

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 40162/3013 (NI)
Vm 40162/5013 (GB)

Pack sizes:
1 box with 1 blister of 2 chewable tablets
1 box with 1 blister of 4 chewable tablets
1 box with 12 blisters, each blister contains 4 chewable tablets
1 box with 24 blisters, each blister contains 4 chewable 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
C&H Generics Ltd
c/o Michael McEvoy & Co.
Seville House
New Dock Street
Galway
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.

Gavin Hall

Approved: 23 October 2025