PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MiPet Easecto 10 mg chewable tablets for dogs >2.5–5 kg

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

sarolaner 10 mg

3. PACKAGE SIZE

3 tablets

4. TARGET SPECIES

Dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBER

Vm 42058/5034

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

Veterinary medicinal product subject to prescription.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MiPet Easecto

2. QUALITITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

10 mg

>2.5–5 kg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MiPet Easecto 10 mg chewable tablets for dogs >2.5–5 kg

2. COMPOSITION

Each tablet contains:

MiPet Easecto chewable tablets	sarolaner (mg)
for dogs 1.3–2.5 kg	5
for dogs >2.5–5 kg	10
for dogs >5–10 kg	20
for dogs >10–20 kg	40
for dogs >20–40 kg	80
for dogs >40–60 kg	120

Mottled brown coloured, square shaped chewable tablets with rounded edges. The number embossed on one side refers to the strength (mg) of the tablet: “5”, “10”, ”20”, “40”, “80” or “120”.

3. TARGET SPECIES

Dogs.

4. INDICATIONS FOR USE

For the treatment of tick infestations (*Dermacentor reticulatus, Ixodes hexagonus, Ixodes ricinus* and *Rhipicephalus sanguineus*). The veterinary medicinal product has immediate and persistent tick killing activity for at least 5 weeks.

For the treatment of flea infestations (*Ctenocephalides felis* and *Ctenocephalides canis*). The veterinary medicinal product has immediate and persistent flea killing activity against new infestations for at least 5 weeks. The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

For the treatment of sarcoptic mange (*Sarcoptes scabiei*).

For the treatment of ear mite infestations (*Otodectes cynotis*).

For the treatment of demodicosis (*Demodex canis*).

For reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for 28 days after treatment. The effect is indirect due to the veterinary medicinal product’s activity against the vector.

Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. SPECIAL WARNING(S)

Special warnings:
Transmission of *B. canis canis* cannot be completely excluded since *D. reticulatus* ticks have to attach to the host before being killed. As an acaricidal effect against *D. reticulatus* may take up to 48 hours, transmission of *B. canis canis* during the first 48 hours cannot be excluded.

The use of the veterinary medicinal product should be based on the local epidemiological situation including knowledge of the prevalent tick species as transmission of *B. canis* by tick species other than *D. reticulatus* is possible and should be part of an integrated control program to prevent the transmission of *Babesia canis*.

Special precautions for safe use in the target species:
Puppies less than 8 weeks of age and/or dogs less than 1.3 kg bodyweight should not be treated unless so advised by a veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after handling the veterinary medicinal product.
The accidental ingestion of the veterinary medicinal product may potentially result in adverse effects, such as transient excitatory neurological signs.
To prevent children from accessing the veterinary medicinal product, only one chewable tablet at a time should be removed from the blister pack and only when required. The blister pack should be returned into the carton immediately after use and the carton should be stored out of the sight and reach of children. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation or in animals intended for breeding. Laboratory studies in rats and rabbits have not produced any evidence of any teratogenic effects. The use in these animals is not recommended.

Fertility:
The safety of the veterinary medicinal product has not been established in dogs intended for breeding. The use in these animals is not recommended.

Interaction with other medicinal products and other forms of interactions:
None known.

During clinical field trials, no interactions between this veterinary medicinal product and routinely used veterinary medicinal products were observed.

In laboratory safety studies, no interactions were observed when sarolaner was co-administered with milbemycin oxime, moxidectin and pyrantel pamoate. (In these studies efficacy was not investigated).
Sarolaner is highly bound to plasma proteins and might compete with other highly bound drugs such as non-steroidal anti-inflammatory drugs (NSAIDs) and the cumarin derivative warfarin.

Overdose:
In a margin of safety study, the veterinary medicinal product was administered orally to 8 week old Beagle puppies at doses of 0, 1, 3, and 5 times the maximum exposure dose of 4 mg/kg at 28 day intervals for 10 doses. No adverse effects were observed at the maximum exposure dose of 4 mg/kg. In the overdose groups, transient and self-limiting neurological signs were observed in some animals: mild tremors at 3 times the maximum exposure dose and convulsions at 5 times the maximum exposure dose. All dogs recovered without treatment.

Sarolaner is well tolerated in Collies with a deficient multidrug-resistance-protein 1 (MDR1 -/-) following single oral administration at 5 times the recommended dose. No treatment-related clinical signs were observed.

7. ADVERSE EVENTS

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
gastrointestinal signs (vomiting, diarrhoea)[1], systemic disorders (lethargy, anorexia)[1], neurological signs (tremor, ataxia, convulsions)[2]

[1]Mild and transient.
[2]In most cases these signs are transient.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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.

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

For oral use.

The veterinary medicinal product should be administered at a dose of 2–4 mg/kg bodyweight in accordance with the following table:

Bodyweight (kg)	Tablet strength (mg sarolaner)	Number of tablets to be administered
1.3–2.5	5	One
>2.5–5	10	One
>5–10	20	One
>10–20	40	One
>20–40	80	One
>40–60	120	One
>60	Appropriate combination of tablets	

Use appropriate combination of available strengths to achieve the recommended dose of 2–4 mg/kg. To ensure a correct dosage, bodyweight should be determined as accurately as possible. The tablets should not be divided.

Tablets can be administered with or without food.

Treatment schedule:
For optimal control of flea and tick infestations, the veterinary medicinal product should be administered at monthly intervals and continue throughout the flea and/or tick season based on the local epidemiological situation.

For the treatment of ear mite infestations (*Otodectes cynotis*) a single dose should be administered. A further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

For the treatment of sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*) a single dose should be administered at monthly intervals for two consecutive months.

For the treatment of demodicosis (caused by *Demodex canis*) the administration of a single dose once monthly for three consecutive months is efficacious and leads to a marked improvement of clinical signs. Treatment should be continued until skin scrapings are negative on at least two consecutive occasions one month apart. As demodicosis is a multi-factorial disease, it is advisable to also treat any underlying disease appropriately.

9. ADVICE ON CORRECT ADMINISTRATION

The tablets of this veterinary medicinal product are chewable and palatable and readily consumed by dogs when offered by the owner. If the tablet is not taken up voluntarily by the dog it can also be given with food or directly into the mouth.

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 storage conditions. Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the blister after Exp. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. These measures should help to protect the environment.

Ask your veterinary surgeon 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 42058/5034

For each strength, the chewable tablets are available in a carton with 1 blister of 3 tablets.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

Find more product information by search for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

Local representatives and contact details to report suspected adverse reactions:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey, KT22 7LP
UK
Tel: +44 (0) 345 300 8034

17. OTHER INFORMATION

Sarolaner is an acaricide and insecticide belonging to the isoxazoline family. Sarolaner is active against adult fleas (*Ctenocephalides felis* and *Ctenocephalides canis*) as well as several tick species such as *Dermacentor reticulatus, Ixodes hexagonus, Ixodes ricinus*, *Rhipicephalus sanguineus* and the mites *Demodex canis*, *Otodectes cynotis* and *Sarcoptes scabiei*.

For fleas, the onset of efficacy is within 8 hours of attachment during the 28 day period after product administration. For ticks (*I. ricinus*), the onset of efficacy is within 12 hours of attachment during the 28 day period after product administration. Ticks on the animal prior to administration are killed within 24 hours.

The veterinary medicinal product kills newly emerged fleas on the dogs before they can lay eggs and therefore it prevents environmental flea contamination in areas to which the dog has access.

Approved 14 September 2023