ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS
1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Simparica 5 mg chewable tablets for dogs 1.3–2.5 kg
Simparica 10 mg chewable tablets for dogs >2.5–5 kg
Simparica 20 mg chewable tablets for dogs >5–10 kg
Simparica 40 mg chewable tablets for dogs >10–20 kg
Simparica 80 mg chewable tablets for dogs >20–40 kg
Simparica 120 mg chewable tablets for dogs >40–60 kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

<table>
<thead>
<tr>
<th>Simparica chewable tablets</th>
<th>sarolaner (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>for dogs 1.3–2.5 kg</td>
<td>5</td>
</tr>
<tr>
<td>for dogs &gt;2.5–5 kg</td>
<td>10</td>
</tr>
<tr>
<td>for dogs &gt;5–10 kg</td>
<td>20</td>
</tr>
<tr>
<td>for dogs &gt;10–20 kg</td>
<td>40</td>
</tr>
<tr>
<td>for dogs &gt;20–40 kg</td>
<td>80</td>
</tr>
<tr>
<td>for dogs &gt;40–60 kg</td>
<td>120</td>
</tr>
</tbody>
</table>

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablets.
Mottled brown coloured, square shaped chewable tablets with rounded edges.

The number embossed on one side refers to the strength (mg) of the tablets: “5”, “10”, “20”, “40”, “80” or “120”.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

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*).

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

### 4.3 Contraindications

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

### 4.4 Special warnings

Parasites need to start feeding on the host to become exposed to sarolaner; therefore, the transmission of infectious parasite-borne diseases cannot be excluded.

### 4.5 Special precautions for use

**Special precautions for use in animals**

In the absence of available data, treatment of puppies less than 8 weeks of age and/or dogs less than 1.3 kg bodyweight should be based on a benefit-risk assessment by the responsible veterinarian.

**Special precautions to be taken by the person administering the veterinary medicinal product to animals**

Wash hands after handling the product.

The accidental ingestion of the product may potentially result in adverse effects, such as transient excitatory neurological signs. To prevent children from accessing the product, only one chewable tablet at a time should be removed from the blister pack and only when required. The blister pack should then 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 label to the physician.

### 4.6 Adverse reactions (frequency and seriousness)

In very rare cases adverse reactions associated with mild and transient gastrointestinal effects such as vomiting and diarrhoea may occur. In very rare cases transient neurological disorders such as tremor, ataxia or convulsion may occur. These signs typically resolve without treatment.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

### 4.7 Use during pregnancy, lactation or lay

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. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.
4.8 Interaction with other medicinal products and other forms of interaction

None known.

During clinical field trials, no interactions between Simparica chewable tablets for dogs 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.

4.9 Amounts to be administered and administration route

For oral use.
Tablets can be administered with or without food.

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

<table>
<thead>
<tr>
<th>Bodyweight (kg)</th>
<th>Tablet strength (mg sarolaner)</th>
<th>Number of tablets to be administered</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3–2.5</td>
<td>5</td>
<td>One</td>
</tr>
<tr>
<td>&gt;2.5–5</td>
<td>10</td>
<td>One</td>
</tr>
<tr>
<td>&gt;5–10</td>
<td>20</td>
<td>One</td>
</tr>
<tr>
<td>&gt;10–20</td>
<td>40</td>
<td>One</td>
</tr>
<tr>
<td>&gt;20–40</td>
<td>80</td>
<td>One</td>
</tr>
<tr>
<td>&gt;40–60</td>
<td>120</td>
<td>One</td>
</tr>
<tr>
<td>&gt;60</td>
<td>Appropriate combination of tablets</td>
<td></td>
</tr>
</tbody>
</table>

Use appropriate combination of available strengths to achieve the recommended dose of 2–4 mg/kg.

Simparica tablets 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. The tablets should not be divided.

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

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.
4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for systemic use.
ATC vet code: QP53BE03.

5.1 Pharmacodynamic properties

Sarolaner is an acaricide and insecticide belonging to the isoxazoline family. The primary target of action of sarolaner in insects and acarines is functional blockade of ligand-gated chloride channels (GABA-receptors and glutamate-receptors). Sarolaner blocks GABA- and glutamate-gated chloride channels in the central nervous system of insects and acarines. Disruption of these receptors by sarolaner prevents the uptake of chloride ions by GABA and glutamate gated ion channels, thus resulting in increased nerve stimulation and death of the target parasite. Sarolaner exhibits higher functional potency to block insect/acarine receptors compared to mammalian receptors. Sarolaner does not interact with known insecticidal binding sites of nicotinic or other GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes. 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 dog before they can lay eggs and therefore it prevents environmental flea contamination in areas to which the dog has access.

5.2 Pharmacokinetic particulars

The bioavailability of sarolaner following oral dosing was high at >85%. Sarolaner was dose proportional in Beagle dogs when dosed from the intended use dose of 2–4 mg/kg, to 20 mg/kg. The prandial state of the dog does not significantly affect the extent of its absorption.

Sarolaner was determined to have low clearance (0.12 ml/min/kg) and a moderate volume of distribution (2.81 l/kg). Half-life was comparable for the intravenous and oral routes at 12 and 11 days, respectively. Plasma protein binding was determined in vitro and calculated at ≥99.9%. 
A distribution study determined that $^{14}$C-sarolaner-related residues were widely distributed to the tissues. The depletion from tissues was consistent with the plasma half-life.

The primary route of elimination is biliary excretion of parent molecule, with elimination through the faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypermellose acetate succinate, medium grade
Lactose monohydrate
Sodium starch glycolate
Silica, colloidal anhydrous
Magnesium stearate
Maize starch
Confectioner’s sugar
Glucose, liquid (81.5% solids)
Spray dried pork liver powder
Hydrolysed vegetable protein
Gelatin type A
Wheat germ
Calcium hydrogen phosphate anhydrous

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 30 months.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Aluminium foil/foil blister package.
One carton contains one blister of 1, 3 or 6 tablets.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
7. MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/15/191/001-018

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06/11/2015.

10. DATE OF REVISION OF THE TEXT

{DD/MM/YYYY}
Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.emea.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.
ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs
A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Zoetis Belgium SA
Rue Laid Burniat, 1
1348 Louvain-la-Neuve
BELGIUM

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.
ANNEX III

LABELLING AND PACKAGE LEAFLET
A. LABELLING
PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Simparica 5 mg chewable tablets for dogs 1.3–2.5 kg
Simparica 10 mg chewable tablets for dogs >2.5–5 kg
Simparica 20 mg chewable tablets for dogs >5–10 kg
Simparica 40 mg chewable tablets for dogs >10–20 kg
Simparica 80 mg chewable tablets for dogs >20–40 kg
Simparica 120 mg chewable tablets for dogs >40–60 kg

sarolaner

2. STATEMENT OF ACTIVE SUBSTANCES

sarolaner 5 mg
sarolaner 10 mg
sarolaner 20 mg
sarolaner 40 mg
sarolaner 80 mg
sarolaner 120 mg

3. PHARMACEUTICAL FORM

Chewable tablets

4. PACKAGE SIZE

1 tablet
3 tablets
6 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/15/191/001 (5 mg, 1 tablet)
EU/2/15/191/002 (5 mg, 3 tablets)
EU/2/15/191/003 (5 mg, 6 tablets)
EU/2/15/191/004 (10 mg, 1 tablet)
EU/2/15/191/005 (10 mg, 3 tablets)
EU/2/15/191/006 (10 mg, 6 tablets)
EU/2/15/191/007 (20 mg, 1 tablet)
EU/2/15/191/008 (20 mg, 3 tablets)
EU/2/15/191/009 (20 mg, 6 tablets)
EU/2/15/191/010 (40 mg, 1 tablet)
EU/2/15/191/011 (40 mg, 3 tablets)
EU/2/15/191/012 (40 mg, 6 tablets)
EU/2/15/191/013 (80 mg, 1 tablet)
EU/2/15/191/014 (80 mg, 3 tablets)
EU/2/15/191/015 (80 mg, 6 tablets)
EU/2/15/191/016 (120 mg, 1 tablet)
EU/2/15/191/017 (120 mg, 3 tablets)
EU/2/15/191/018 (120 mg, 6 tablets)

17. MANUFACTURER’S BATCH NUMBER

Lot {number}
MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Simparica 5 mg
Simparica 10 mg
Simparica 20 mg
Simparica 40 mg
Simparica 80 mg
Simparica 120 mg
sarolaner

1.3–2.5 kg
>2.5–5 kg
>5–10 kg
>10–20 kg
>20–40 kg
>40–60 kg

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
B. PACKAGE LEAFLET
1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Simparica 5 mg chewable tablets for dogs 1.3–2.5 kg
Simparica 10 mg chewable tablets for dogs >2.5–5 kg
Simparica 20 mg chewable tablets for dogs >5–10 kg
Simparica 40 mg chewable tablets for dogs >10–20 kg
Simparica 80 mg chewable tablets for dogs >20–40 kg
Simparica 120 mg chewable tablets for dogs >40–60 kg

sarolaner

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each tablet contains:

<table>
<thead>
<tr>
<th>Simparica chewable tablets</th>
<th>sarolaner (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>for dogs 1.3–2.5 kg</td>
<td>5</td>
</tr>
<tr>
<td>for dogs &gt;2.5–5 kg</td>
<td>10</td>
</tr>
<tr>
<td>for dogs &gt;5–10 kg</td>
<td>20</td>
</tr>
<tr>
<td>for dogs &gt;10–20 kg</td>
<td>40</td>
</tr>
<tr>
<td>for dogs &gt;20–40 kg</td>
<td>80</td>
</tr>
<tr>
<td>for dogs &gt;40–60 kg</td>
<td>120</td>
</tr>
</tbody>
</table>

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”.

4. INDICATION(S)

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*).

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 case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

In very rare cases adverse reactions associated with mild and transient gastrointestinal effects such as vomiting and diarrhoea may occur. In very rare cases transient neurological disorders such as tremor, ataxia or convulsion may occur. These signs typically resolve without treatment.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

If you notice any serious effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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:

<table>
<thead>
<tr>
<th>Bodyweight (kg)</th>
<th>Tablet strength (mg sarolaner)</th>
<th>Number of tablets to be administered</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3–2.5</td>
<td>5</td>
<td>One</td>
</tr>
<tr>
<td>&gt;2.5–5</td>
<td>10</td>
<td>One</td>
</tr>
<tr>
<td>&gt;5–10</td>
<td>20</td>
<td>One</td>
</tr>
<tr>
<td>&gt;10–20</td>
<td>40</td>
<td>One</td>
</tr>
<tr>
<td>&gt;20–40</td>
<td>80</td>
<td>One</td>
</tr>
<tr>
<td>&gt;40–60</td>
<td>120</td>
<td>One</td>
</tr>
<tr>
<td>&gt;60</td>
<td>Appropriate combination of tablets</td>
<td></td>
</tr>
</tbody>
</table>

Use appropriate combination of available strengths to achieve the recommended dose of 2–4 mg/kg. 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**

Simparica tablets 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 PERIOD(S)**

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 blister after EXP.

12. **SPECIAL WARNING(S)**

_Special warnings for each target species:_
Parasites need to start feeding on the host to become exposed to sarolaner; therefore, the transmission of infectious parasite-borne diseases cannot be excluded.

_Special precautions for use in animals:_
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 product.
The accidental ingestion of the product may potentially result in adverse effects, such as transient excitatory neurological signs. To prevent children from accessing the 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 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. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

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

During clinical field trials, no interactions between Simparica chewable tablets for dogs 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 (symptoms, emergency procedures, antidotes):**
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.

13. **SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. **DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**


15. **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.

For each strength, the chewable tablets are available in the following pack sizes: carton with 1 blister 
of 1, 3 and 6 tablets. Not all pack sizes may be marketed.

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

**België/Belgique/Belgien**
Zoetis Belgium SA
Tél/Tel.: +32 (0) 800 99 189

**Lietuva**
Oriola Vilnius UAB
Tel: +370 610 05088

**Република България**
Zoetis Belgium SA
Tel: +359 2 4775791

**Luxembourg/Luxemburg**
Zoetis Belgium SA
Tél/Tel.: +352 8002 4026

**Ц eská republika**
Zoetis Česká republika, s.r.o.
Tel: +420 257 101 111

**Magyarország**
Zoetis Hungary Kft.
Tel: +361 224 5222

**Danmark**
Orion Pharma Animal Health
Tlf: +45 86 14 00 00

**Malta**
Agrimed Limited
Tel: +356 21 465 797

**Deutschland**
Zoetis Deutschland GmbH
Tel: +49 30 330063 0

**Nederland**
Zoetis B.V.
Tel: +31 (0)10 714 0900

**Eesti**
Oriola Vilnius UAB
Tel: +370 610 05088

**Norge**
Orion Pharma Animal Health
Tlf: +47 40 00 41 90

**Ελλάδα**
Zoetis Hellas S.A.
Τηλ.: +30 210 6791900

**Österreich**
Zoetis Österreich GmbH
Tel: +43 1 2701100 110

**España**
Zoetis Spain, S.L.
Tel: +34 91 4191900

**Polska**
Zoetis Polska Sp. z o.o.
Tel: +48 22 2234800

**France**
Zoetis France
Tél: +33 (0)810 734 937

**Portugal**
Zoetis Portugal, Lda.
Tel: +351 21 042 72 00
Hrvatska
Zoetis B.V., Podružnica Zagreb za promidžbu
Tel: +385 1 644 1460

România
Zoetis România SRL
Tel: +40 21 202 3083

Ireland
Zoetis Belgium SA
Tel: +353 (0) 1 256 9800

Slovenija
Zoetis B.V., Podružnica Zagreb za promidžbu
Tel: +385 1 644 1460

Ísland
Icepharma hf.
Sími: +354 540 80 00

Slovenská republika
Zoetis Česká republika, s.r.o.
Tel: +420 257 101 111

Italia
Zoetis Italia S.r.l.
Tel: +39 06 3366 8133

Suomi/Finland
Zoetis Finland Oy
Puh/Tel: +358 (0)9 4300 40

Κύπρος
Zoetis Hellas S.A.
Τηλ.: +30 210 6791900

Sverige
Orion Pharma Animal Health
Tel: +46 (0)8 623 64 40

Latvija
Oriola Vilnius UAB
Tel: +370 610 05088

United Kingdom
Zoetis UK Limited
Tel: +44 (0) 845 300 8034