ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Borrelym 3, suspension for injection for dogs
(in CZ, EE, HU, LT, LV, PL, RO, SI, SK)
Merilym 3, suspension for injection for dogs
(in AT, BE, DE, FR, IE, IT, LU, NL, PT, UK)
Trilyme, suspension for injection for dogs
(in DK, FI, NO, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition of one dose (1 ml):

Active substances:
Inactivated *Borrelia burgdorferi sensu lato*:
Borrelia garinii .....RP ≥ 1*
Borrelia afzelii .....RP ≥ 1*
Borrelia burgdorferi sensu stricto .....RP ≥ 1*
*RP = Relative potency (ELISA test) compared with the reference serum obtained after vaccination of mice with a vaccine batch that has successfully passed the challenge test in the target species.

Adjuvant:
Aluminium (as hydroxide).....2 mg

Excipients:
Formaldehyde .....max. 0.5 mg
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Pinkish up to white fluid containing white sediment that disperses easily when the content is shaken.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For active immunization of dogs from 12 weeks of age, to induce an anti-OspA response against *Borrelia spp.* (*B. burgdorferi sensu stricto*, *B. garinii* and *B. afzelii*).

Reduction of *Borrelia* transmission was only investigated under laboratory conditions, following a challenge with field ticks (collected from a region known to be affected by *Borrelia*). Under these conditions, it was shown that no *Borrelia* could be isolated from the skin of vaccinated dogs, while *Borrelia* were isolated from the skin of non vaccinated dogs.

Reduction of transmission of *Borrelia* from the tick to the host has not been quantified, and no correlation has been established between a specific level of antibodies and reduction of *Borrelia* transmission. The efficacy of the vaccine against an infection that leads to the development of clinical disease has not been studied.

Onset of immunity: 1 month after primary vaccination.
Duration of immunity: one year after primary vaccination.

4.3 Contraindications

Do not use in case of general febrile illness.
Do not use in sick animals that have intercurrent disease, heavy parasitic infestation and/or are in poor general condition.
Do not use in case of suspected or confirmed clinical Lyme borreliosis.
Do not use in case of hypersensitivity to the active substances, to the adjuvant or to any of the excipients.

4.4 Special warnings for each target species

Vaccinate healthy animals only.
No information is available on the use of the vaccine in seropositive animals including those with maternally derived antibodies.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Transitory swelling of up to 7 cm in diameter may be observed at the injection site for up to 5 days in rare cases. Anorexia or lethargy can be observed after treatment rarely.
Swellings of larger diameter (up to 15 cm) have been observed in very rare cases. A transient increase in body temperature (up to 1.5°C) may be induced very rarely.
A hypersensitivity reaction may occur in very rare cases, which may require appropriate symptomatic 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

Safety of the veterinary medicinal product has not been established during pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

Dose:
1 ml from 12 weeks of age.

Method of administration:
Subcutaneously.

Shake the vial well before use.

Primary vaccination:
Administer two doses separated by an interval of 3 weeks.

Revaccination:
Annual revaccination with a single dose is recommended to maintain immunity although this schedule has not been investigated.

Vaccination should be carried out prior to periods of increased tick activity, allowing sufficient time for the immune response to vaccination to develop fully (see section 4.2) prior to expected tick exposure.

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

No other adverse reactions than those described in section 4.6 were observed after administration of a double dose.

4.11 Withdrawal periods

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: inactivated bacterial vaccines - borrelia
ATCvet code: QI07AB04

The vaccine induces specific anti-OspA antibodies against *Borrelia burgdorferi sensu lato*. Scientific literature are available which indicate that during a tick blood feeding, vaccine-induced antibodies present in the blood are ingested by the tick and are expected to bind to OspA proteins expressed by the bacteria in the tick gut; this is expected to reduce their migration to the salivary glands and transmission to the host.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide hydrated for adsorption
Formaldehyde
Sodium chloride
Potassium dihydrogen phosphate
Disodium hydrogen phosphate dodecahydrate
Water for injection

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: use immediately after opening.

6.4 Special precautions for storage

Protect from light.
Store and transport refrigerated (2 °C – 8 °C).

6.5 Nature and composition of immediate packaging

The vaccine is presented in hydrolytic class I glass vials. The vials are sealed with pierceable rubber stoppers and secured with aluminium caps. Glass vials are packed in plastic boxes.

A) Plastic box with 10 wells:
10 x 1 ml of the vaccine
2 x 1 ml of the vaccine

B) Plastic box with 20 wells:
20 x 1 ml of the vaccine

C) Plastic box with 100 wells:
100 x 1 ml of the vaccine
50 x 1 ml of the vaccine

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 product

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

To be completed nationally.

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD/MM/YYYY
To be completed nationally.

10. DATE OF REVISION OF THE TEXT

DD month YYYY
To be completed nationally.

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.