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, LU, PT, UK(NI))
Trilyme suspension for injection for dogs
(in DK, NO, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) contains:

Active substances:
Borrelia burgdorferi sensu lato:
Borrelia garinii, strain BR14, inactivated RP ≥ 1*
Borrelia afzelii, strain BR33, inactivated RP ≥ 1*
Borrelia burgdorferi, strain DSM 4681, inactivated 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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Formaldehyde	max. 0.5 mg
Sodium chloride	
Potassium dihydrogen phosphate	
Disodium hydrogen phosphate dodecahydrate	
Water for injection	

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For active immunization of dogs from 12 weeks of age, to induce an anti-OspA response against *Borrelia* spp. (*B. burgdorferi*, *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: 1 year after primary vaccination.

3.3 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 cases of hypersensitivity to the active substances, to the adjuvant or to any of the excipients.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

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

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):	Injection site swelling.[1] Anorexia, lethargy.
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Injection site swelling.[2] Elevated temperature.[3] Hypersensitivity reaction.[4]

[1] Up to 7 cm in diameter, for up to 5 days.
[2] Up to 15 cm in diameter.
[3] Transient, up to 1.5°C.
[4] Which may require appropriate symptomatic treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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.

3.9 Administration routes and dosage

Dose:
1 ml from 12 weeks of age.

Method of administration:
Subcutaneous use.
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 3.2) prior to expected tick exposure.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No other adverse events than those described in section 3.6 were observed after administration of a double dose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

Pack sizes:

Plastic box with 10 wells:
10 vials of 1 ml of the vaccine
2 vials of 1 ml of the vaccine

Plastic box with 20 wells:
20 vials of 1 ml of the vaccine

Plastic box with 100 wells:
100 vials of 1 ml of the vaccine
50 vials of 1 ml of the vaccine

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

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

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

To be completed nationally.

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

2 x 1 ml, 10 x 1 ml, 20 x 1 ml, 50 x 1 ml, 100 x 1 ml
Plastic box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Per 1 d. (1 ml):
Inactivated *Borrelia burgdorferi sensu lato*:

Borrelia garinii	RP ≥ 1
Borrelia afzelii	RP ≥ 1
Borrelia burgdorferi	RP ≥ 1

3. PACKAGE SIZE

2 x 1 ml
10 x 1 ml
20 x 1 ml
50 x 1 ml
100 x 1 ml

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

Protect from light.
Store and transport refrigerated.

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

To be completed nationally

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Borrelym 3 (in CZ, EE, HU, LT, LV, PL, RO, SI, SK)
Merilym 3 (in AT, BE, DE, FR, IE, LU, PT, UK(NI))
Trilyme (in DK, NO, SE)

{logo}

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 d. (1 ml)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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, LU, PT, UK(NI))
Trilyme suspension for injection for dogs (in DK, NO, SE)

2. Composition

Each dose (1 ml) contains:

Active substances:
Borrelia burgdorferi sensu lato:

Borrelia garinii, strain BR14, inactivated	RP ≥ 1*
Borrelia afzelii, strain BR33, inactivated	RP ≥ 1*
Borrelia burgdorferi, strain DSM 4681, inactivated	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

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

3. Target species

Dogs.

4. Indications for use

For active immunization of dogs from 12 weeks of age, to induce an anti-OspA response against *Borrelia* spp. (*B. burgdorferi*, *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:	1 year after primary vaccination.

5. 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 Lyme borreliosis.
Do not use in cases of hypersensitivity to the active substances, to the adjuvant or to any of the excipients.

6. Special warnings

Vaccinate healthy animals only.

Special precautions for safe use in the target species:
No information is available on the use of the vaccine in seropositive animals including those with maternally derived antibodies.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

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.

Overdose:
No other adverse events than those described in section "Adverse events" were observed after administration of a double dose.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Dogs:
Rare (1 to 10 animals / 10 000 animals treated):
Injection site swelling.[1] Anorexia (loss of appetite), lethargy.
Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Injection site swelling.[2] Elevated temperature.[3] Hypersensitivity reaction.[4]

[1] Up to 7 cm in diameter, for up to 5 days.
[2] Up to 15 cm in diameter.
[3] Transient, up to 1.5°C.
[4] Which may require appropriate symptomatic treatment.

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: {national system details}.

8. Dosage for each species, routes and method of administration

Dose:
1 ml from 12 weeks of age.

Method of administration:
Subcutaneous 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) prior to expected tick exposure.

9. Advice on correct administration

Shake the vial well before use.

10. Withdrawal period

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label 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 or household waste.

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

MA numbers: To be completed nationally.

Pack sizes:

Plastic box with 10 wells containing:
10 vials of 1 ml of the vaccine
2 vials of 1 ml of the vaccine

Plastic box with 20 wells:
20 vials of 1 ml of the vaccine

Plastic box with 100 wells:
100 vials of 1 ml of the vaccine
50 vials of 1 ml of the vaccine

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
To be completed nationally.

Manufacturer responsible for batch release:
Bioveta a.s.
Komenského 212/12
683 23 Ivanovice na Hané
Czechia

Local representatives and contact details to report suspected adverse reactions:
To be completed nationally.

17. Other information

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.