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

Merilym 3, suspension for injection for dogs

2. STATEMENT OF THE ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACK SIZE

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

5. TARGET SPECIES

Dogs.

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Method of administration:
subcutaneous use

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Use immediately after opening.

11. SPECIAL STORAGE CONDITIONS

Protect from light.
Store and transport refrigerated.

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

Read the package leaflet before use.

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue

Bracknell
Berkshire
RG12 8YS
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4254

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{1 ml / label**}**

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, IT, LU, NL, PT, UK)
Trilyme (in DK, FI, NO, SE)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Read the package leaflet before use.

3. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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)

1. NAME AND ADDRESS OF MARKETING AUTHORISATION HOLDER AND OF MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

In CZ, EE, HU, LT, LV, PL, RO, SI, SK:
Marketing Authorisation Holder and Manufacturer:
Bioveta, a.s., Komenského 212/12, 683 23 Ivanovice na Hané, Czech Republic

In AT, BE, DE, DK, FI, FR, IE, IT, LU, NL, NO, PT, SE, UK:
Marketing Authorisation Holder:
Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

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

2. 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)

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

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

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

4. INDICATION(S)

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.

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

6. ADVERSE REACTIONS

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)

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 inform your veterinary surgeon. Alternatively you can report via your national reporting system.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dose:
1 ml from 12 weeks of age.

Method of administration:
Subcutaneously.

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 after expiry date stated on the label.
Shelf life after first opening the container: use immediately after opening.

12. SPECIAL WARNING(S)

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.

Use during pregnancy, lactation:
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 product when used with any other veterinary medicinal products. 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.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD/MM/YYYY

15. 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.

Vial:
2 x 1 ml of the vaccine
10 x 1 ml of the vaccine
20 x 1 ml of the vaccine
50 x 1 ml of the vaccine
100 x 1 ml of the vaccine

Not all pack sizes may be marketed.

Approved: 02 September 2019