

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}

