SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Merilym 3, suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose 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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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, 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.

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 cases 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.

4.5 Special precautions for use

Special precautions for use in animals
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.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

The 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 Amount(s) to be administered and administration route

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 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 period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

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

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.

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.

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.

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

Medicines should not be disposed of via wastewater.

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

Boehringer Ingelheim Animal Health UK Limited

8. MARKETING AUTHORISATION NUMBER

Vm 08327/5035

9. DATE OF FIRST AUTHORISATION

02 May 2013

10. DATE OF REVISION OF THE TEXT

July 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

Gavin Hall
Approved: 23 January 2025