1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ByeMite 500 mg/ml concentrate for spraying emulsion for laying hens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Phoxim 500 mg

Excipients:

Qualitative composition of excipients and other constituents
n-Butanol
Calcium salt of Dodecylbenzolsulphonic acid
p-Methylphenylethyl(2,7)-phenoxy-polyglycol(27)-ether
p-Methylphenylethyl(2,7)-phenoxy-polyglycol(17)-ether
Xylene
Methylisobutylketone

Clear slightly yellow to brown liquid.

3. CLINICAL INFORMATION

3.1 Target species

Laying hens.

3.2 Indications for use for each target species

Treatment of infestations of poultry red mites (*Dermanyssus gallinae*) sensitive to organophosphates, in the rearing buildings of pullets and laying hens, in the presence of the animals.

3.3 Contraindications

Do not use in broiler farms.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

As the mites do not parasite the hens constantly but hide and multiply in habitats a short distance away from them, it is critically important during the manual and automated spraying procedures to direct the spray cone not directly onto the hens, but onto the cages, the battery infrastructure and auxiliaries (metal posts, feed troughs, egg conveyor belts etc.) near the hens.

Birds are very sensitive to organophosphates and should not be exposed directly to the veterinary medicinal product. Do not spray directly onto the birds. The veterinary medicinal product should be sprayed carefully to avoid inhalation of spray mist by hens. Oral intake of spray solution by hens must be prevented. Remove feed and eggs before treatment. Any loose litter in the laying nests should be removed before spray application. Discard eggs laid during and on the same day after the treatment.

Cleaning, disinfection and killing of mites in the empty poultry house are important steps for the control of *Dermanyssus gallinae*. In addition, any introduction of new mites into a poultry house by contaminated materials or people, wild birds or rodents, should be prevented. Use of this veterinary medicinal product should be restricted to those cases where its use is unavoidable because the *Dermanyssus* infestation has become overwhelming.

The veterinary medicinal product should not be sprayed within one month before the planned cleaning of the facility.

Too frequent and repeated use of ectoparasiticides from the same class, over an extended period of time, should be avoided. Indeed, those practices increase the risk of development of resistance and could ultimately result in ineffective therapy.

As with other parasites, resistance to acaricides in populations of mites results from the selection of individuals with lower inherent susceptibility, following exposure to these acaricides. Resistance development can be accelerated if less than effective application doses are used.

To delay the development of phoxim-resistant *Dermanyssus* strains, it is recommended to:

- limit the treatment of poultry houses to cases where it becomes unavoidable, to maintain animal welfare conditions, or for economic reasons.
- carefully clean and disinfect the poultry house during the sanitary downtime period.
- calculate the dose precisely and prepare a sufficient quantity of product.
- pay particular attention to ensuring that all surfaces and hiding places around the hens are sufficiently saturated with the solution.

In case of a direct contact between bird and the product clinical signs of organophosphate toxicity can be (but may not be limited to): salivation, gasping, diarrhea, miosis, incoordination, muscle weakness, ataxia, tremor, convulsions, dyspnea, bradycardia, paralysis and finally death.

Organophosphate poisoning in a hen may be treated by intramuscular injection of 0.5 to 1.0 mg atropine per kg bodyweight.

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

Phoxim is a skin sensitizer and slightly irritating to the skin and eyes. Persons with known hypersensitivity to the active substance should avoid contact with the product.

Phoxim is an organophosphorus compound. Do not use if under medical advice not to work with such compounds. If you have previously felt unwell after using a product containing an organophosphorus compound, consult your doctor before working with this veterinary medicinal product and show the doctor the product label.

To the physician: Poisoning from organophosphorus compounds results from blockage of acetylcholinesterase, with a resultant over-activity of acetylcholine. Symptoms include headache, exhaustion and weakness, mental confusion together with blurred vision, excessive salivation and sweating, cramp-like abdominal pain, chest tightness, diarrhoea, constricted pupils, and bronchorrhea. These may develop for up to 24 hours after exposure. Severe poisoning can include general muscle twitching, loss of co-ordination, extreme difficulty with breathing and convulsions which may lead to

unconsciousness in the absence of medical treatment. Treat symptomatically and seek urgent hospital transfer if poisoning is suspected.

This product is intended to be applied by veterinarians, pest control operators or by informed farmers, who are advised by a veterinarian. The product should not be used without wearing protective equipment as specified below, whilst handling the product and administering the spray solution. The user must comply with all requirements for protective clothing and follow all user safety recommendations. Ensure that spare protective clothing is available in case any items become damaged. No personnel, with the exception of the spray operator, should be present in the poultry house during spray application. Personnel should not re-enter the poultry house until the morning (or greater than 12 hours) after spray application.

Protective overall with hood:
Category III, type 4 (spray-tight clothing) according to European legislation. Fasten the cuffs of the overalls to the protective gloves with adhesive tape.

Face mask and filter:
Full face mask with combination filter A2P3 or higher. If the characteristic aromatic odour of the product is apparent, check that the mask fits properly and/or change the filter.

Protective gloves:
Nitrile rubber gloves according to EN 374, permeation class 4 (> 120 minutes) or higher.

Adhere to the maximum exposure time, which is specific for the protective equipment.

Product (emulsion concentrate):
Avoid direct contact of the product with the skin. Change the gloves or the protective overall after visible contact with the product. In case of accidental spillage onto the skin wash with water and soap. In case of accidental spillage into the eyes wash with plenty of water.

Spraying solution:
Avoid any contact of the spraying solution with the skin during application and undressing. Wash hands with water and soap after undressing. Do not re-use the protective overall.

Keep the product and the spraying solution away from food, drink and animal feed. When handling the product or the spraying solution do not eat, drink or smoke.

Special precautions for the protection of the environment:
Phoxim is highly toxic to fish and aquatic invertebrates. To reduce the environmental impact of phoxim, restrict the number of annual hen house treatments to 2, i.e. to a total of 4 applications. In addition, when spreading manure derived from treated animals on agricultural land, a safety distance of 10 metres to adjacent surface waters must be kept to avoid exposure of the aquatic environment.

Other precautions:
In case of accidental self-administration, spillage onto skin, seek medical advice immediately and show the package leaflet or the label to the physician.

3.6 Adverse events

Laying hens.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Loss of egg quantity[1]

[1] On the day following product administration.

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

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Spraying use:
The spray solution is sprayed onto the cages in the presence of poultry.

Prepare a spray solution of 2000 ppm phoxim by dilution of the veterinary medicinal product at a rate of 100 ml per 25 l water and stir thoroughly. Apply this spray solution at a rate of 25 l per thousand hen places onto the surfaces that directly surround the hens and were the parasites hide, i.e. cage wires, ancillary equipment, metal posts, feed throughs, conveyor belts, laying nests etc. Use a spray device which delivers coarse spray droplets. Conduct a repeat treatment 7 days later. Prepare the aqueous solution freshly before application. The amount of the spray solution should be calculated carefully and the whole amount should be applied to the treated area. To reduce the environmental impact of phoxim, restrict the number of annual hen house treatments to 2, i.e. to a total of 4 applications.

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

Doubling the recommended dosage does not cause side effects. In one study with 4 times the recommended dosage, sneezing in 60% of the birds and a transient interruption of laying for 2 days in 8% of the birds were observed.

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

Remove eggs before treatment. Discard eggs laid during and on the same day after the treatment.

Eggs:	12 hours
Meat and offal:	25 days after the second treatment

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53AF01

4.2 Pharmacodynamics

Phoxim is an inhibitor of the enzyme cholinesterase (AChE) at the nerve synapses.

The inhibition of the enzyme is irreversible under physiological conditions. Postsynaptic accumulation of acetylcholine interferes with normal impulse transmission in the arthropod's nervous system. A phase of marked hyperexcitation and convulsion is followed by paralysis and death of the parasite.

Phoxim is active against *Dermanyssus gallinae*.
Phoxim is a contact insecticide and the mites are killed whilst and after crawling on those phoxim-treated surfaces.

4.3 Pharmacokinetics

Phoxim is hydrolysed into inactive compounds and excreted chiefly via the feces in the target species.

Environmental properties
Phoxim is highly toxic to fish and aquatic invertebrates. Phoxim is toxic to bees.

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: 30 months.
Shelf life after first opening the immediate packaging: 6 months.
Shelf life after dilution according to directions: 24 hours.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Bottle: COEX (polyethylene/polyamide) with child-proof closure.
Screw cap: polypropylene/polypropylene.
Inner side of sealing disc: polyethylene.

Bottle of 250 ml.
Bottle of 1 l.
Bottle of 5 l.

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.

Phoxim is highly toxic to fish and aquatic invertebrates. The veterinary medicinal product should not enter water courses as phoxim is highly dangerous for fish and other aquatic organisms.

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

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA22020/049/001

8. DATE OF FIRST AUTHORISATION

20/02/2009

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

09/06/2025

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*).