

*[Version 9.1, 11/2024]*

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ByeMite 500 mg/ml concentrate for spraying emulsion for laying hens (BE, BG, CY, CZ, FR, GR, HU, IE, IT, LU, NL, PT, RO, SK, SI)

Baymite vet. 500 mg/ml concentrate for spraying emulsion for laying hens (IS, FI and SE)

## 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 <sup>1</sup>
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<sup>1</sup> 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 where 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**

**7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

DD/MM/YYYY

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

DD month YYYY

**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) (<https://medicines.health.europa.eu/veterinary>).

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**



## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE****CARTON BOX (250 ml)****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

ByeMite 500 mg/ml concentrate for spraying emulsion (BE, BG, CY, CZ, FR, GR, HU, IE, IT, LU, NL, PT, RO, SK, SI)

Baymite vet. 500 mg/ml concentrate for spraying emulsion (IS, FI and SE)

**2. STATEMENT OF ACTIVE SUBSTANCES**

Phoxim 500 mg/ml

**3. PACKAGE SIZE**

250 ml

**4. TARGET SPECIES**

Laying hens.

**5. INDICATIONS****6. ROUTES OF ADMINISTRATION**

Spraying use:

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

**7. WITHDRAWAL PERIODS**

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

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Shelf-life after first opening the bottle: 6 months. Once opened, use by:.....

Shelf life after dilution according to directions: 24 hours.

**9. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25 °C.

**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**

Elanco 

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE****LABEL (250 ml bottle)****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

ByeMite 500 mg/ml concentrate for spraying emulsion (BE, BG, CY, CZ, FR, GR, HU, IE, IT, LU, NL, PT, RO, SK, SI)  
Baymite vet. 500 mg/ml concentrate for spraying emulsion (IS, FI and SE)

**2. STATEMENT OF ACTIVE SUBSTANCES**

Phoxim 500 mg/ml

**3. TARGET SPECIES**

Laying hens.

**4. ROUTES OF ADMINISTRATION**

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

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

**6. EXPIRY DATE**

Exp. {mm/yyyy}

Shelf life after first opening the bottle: 6 months. Once opened, use by:.....

Shelf life after dilution according to directions: 24 hours.

**7. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25 °C

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Elanco logo

<b>9. BATCH NUMBER</b>
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Lot {number}

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

ByeMite 500 mg/ml concentrate for spraying emulsion for laying hens (BE, BG, CY, CZ, FR, GR, HU, IE, IT, LU, NL, PT, RO, SK, SI)

Baymite vet. 500 mg/ml concentrate for spraying emulsion for laying hens (IS, FI and SE)

### 2. Composition

Each ml contains:

**Active substance:**

Phoxim 500 mg

Clear slightly yellow to brown liquid.

### 3. Target species

Laying hens.

### 4. Indications for use

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.

### 5. Contraindications

Do not use in broiler farms.

### 6. Special warnings

Special warnings:

None.

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.

Pregnancy and lactation:

Not applicable.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

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.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

## 7. Adverse events

Laying hens.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Loss of egg quantity <sup>1</sup>
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<sup>1</sup> On the day following product administration.

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 its local representative > 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

Spraying use:

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 where 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.

## 9. Advice on correct administration

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

## 10. 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

## 11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months.

Shelf life after dilution according to directions: 24 hours.

## 12. Special precautions for disposal

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 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**

*To be completed nationally.*

Bottle of 250 ml

Bottle of 1 l

Bottle of 5 l

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

### **16. Contact details**

Marketing authorisation holder <and contact details to report suspected adverse events>:

Manufacturer responsible for batch release:

KVP Pharma + Veterinär Produkte GmbH  
Projensdorfer Str. 324  
24106 Kiel  
Germany

<Local representatives <and contact details to report suspected adverse events>:>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>

### **17. Other information**

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.

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

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET**

**LABEL (250ml, 1000 ml AND 5000 ml BOTTLES)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

ByeMite 500 mg/ml concentrate for spraying emulsion for laying hens (BE, BG, CY, CZ, FR, GR, HU, IE, IT, LU, NL, PT, RO, SK, SI)

Baymite vet. 500 mg/ml concentrate for spraying emulsion for laying hens (IS, FI and SE)

**2. COMPOSITION**

Each ml contains:

**Active substance:**

Phoxim 500 mg

Clear slightly yellow to brown liquid.

**3. PACKAGE SIZE**

1000 ml

5000 ml

250 ml

**4. TARGET SPECIES**

Laying hens.

**5. INDICATIONS FOR USE**

**Indications for use**

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.

**6. CONTRAINDICATIONS**

**Contraindications**

Do not use in broiler farms.

**7. SPECIAL WARNINGS**

**Special warnings**

Special warnings:

None.

### 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.

#### Pregnancy and lactation:

Not applicable.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

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.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

## 8. ADVERSE EVENTS

### Adverse events

Laying hens.

Very rare ( $<1$ animal / 10,000 animals treated, including isolated reports):	Loss of egg quantity <sup>1</sup>
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<sup>1</sup> On the day following product administration.

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 its local representative > using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

## 9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

### Dosage for each species, routes and method of administration

Spraying use:

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 where 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.

## 10. ADVICE ON CORRECT ADMINISTRATION

### Advice on correct administration

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



## **11. WITHDRAWAL PERIODS**

### **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

## **12. SPECIAL STORAGE PRECAUTIONS**

### **Special storage precautions**

Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after Exp. The expiry date refers to the last day of that month.

## **13. SPECIAL PRECAUTIONS FOR DISPOSAL**

### **Special precautions for disposal**

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 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.

## **14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

### **Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

### **Pack sizes**

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

Not all pack sizes may be marketed.

## **16. DATE ON WHICH THE LABEL WAS LAST REVISED**

### **Date on which the label was last revised**

MM/YYYY

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

## 17. CONTACT DETAILS

### Contact details

Marketing authorisation holder <and contact details to report suspected adverse events>:

Manufacturer responsible for batch release:

KVP Pharma + Veterinär Produkte GmbH  
Projensdorfer Str. 324  
24106 Kiel  
Germany

<Local representatives <and contact details to report suspected adverse events>:>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>

## 18. OTHER INFORMATION

### Other information

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.

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

## 19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

## 20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after first opening the bottle: 6 months. Once opened, use by:.....

Shelf life after dilution according to directions: 24 hours.

## 21. BATCH NUMBER

Lot {number}