

## Summary of Product Characteristics

### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

**Active substance:**

Phoxim 500 mg/ml

**Excipient(s):**

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Concentrate for spraying emulsion

Clear slightly yellow to brown liquid

### 4 CLINICAL PARTICULARS

#### 4.1 Target Species

Laying hens.

#### 4.2 Indications for use, specifying the 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.

#### 4.3 Contraindications

Do not use in broiler farms.

#### 4.4 Special warnings for each target species

None.

## 4.5 Special precautions for use

### Special precautions for use in animals

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.

Do not spray directly onto the birds. 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 product should be restricted to those cases where its use is unavoidable because the *Dermanyssus* infestation has become overwhelming.

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

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy: Too frequent and repeated use of ectoparasiticides from the same class, over an extended period of time.

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 that treatment of stocked layer houses should be

- restricted to those cases where a treatment for animal welfare and economic reasons is unavoidable.
- the cleaning and disinfection of the poultry house during the service period must be performed accurately
- the dosing is accurately calculated and a sufficient amount of product is prepared
- it is paid special attention that all surfaces and hiding places around the hens are sufficiently wetted

### 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 product and show the doctor the product label.

Medical Advice to Doctors: 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.

Other precautions

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.

#### **4.6 Adverse reactions (frequency and seriousness)**

The stress reactions caused by the spraying or the temporary withholding of feed during the spraying may cause a minor decrease in egg laying the next day.

#### **4.7 Use during pregnancy, lactation or lay**

Not applicable.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None known.

#### 4.9 Amounts to be administered and administration route

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.

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

#### 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

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

#### 4.11 Withdrawal Period(s)

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

### 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group:	Ectoparasiticides, insecticides and repellents, organophosphorous compounds
ATCvet code:	QP53AF01

#### 5.1 Pharmacodynamic properties

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.

#### 5.2 Pharmacokinetic properties

Phoxim is hydrolysed into inactive compounds and excreted chiefly via the urine.

#### Environmental properties

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

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

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

### 6.2 Incompatibilities

Do not mix with other products.

### 6.3 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.

### 6.4 Special precautions for storage

Do not store above 25 °C.

### 6.5 Nature and composition of immediate packaging

Bottle of 250 mL with child-proof closure Screw cap	COEX (polyethylene/polyamide) polypropylene/polypropylene
Bottle of 1 L with child-proof closure Screw cap	COEX (polyethylene/polyamide) polypropylene/polypropylene
Bottle of 5 L with child-proof closure Screw cap	COEX (polyethylene/polyamide) polypropylene/polyethylene
Inner side of sealing disc	polyethylene

Not all pack sizes may be marketed.

### 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Phoxim is highly toxic to fish and aquatic invertebrates. The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

## **7 MARKETING AUTHORISATION HOLDER**

Bayer Ltd,  
Animal Health Division  
The Atrium,  
Blackthorn Road,  
Dublin 18  
Ireland

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA: 10021/057/001

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 20<sup>th</sup> February 2009

Date of last renewal: 29th November 2013

## **10 DATE OF REVISION OF THE TEXT**

September 2016