

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

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sebacil Pour-on 75 mg/ml pour-on solution for pigs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substances:

Phoxim 75 mg

### Excipients:

Qualitative composition of excipients and other constituents
Paraffin, light liquid
Isopropyl alcohol
Patent blue V (E 131)
1-Butanol

Blue solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Pigs.

### 3.2 Indications for use for each target species

For the treatment of mange (*Sarcoptes scabiei* var. *suis*) and lice infestations (*Haematopinus suis*) in pigs.

### 3.3 Contraindications

Do not use the veterinary medicinal product on sick or highly stressed animals or during convalescence. Do not use in cases of hypersensitivity to organophosphates or to any of the excipients.

### 3.4 Special warnings

None.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

See section 3.8, "Interaction with other medicinal products and other forms of interaction". Particular caution is indicated when using the veterinary medicinal product on animals with heart failure, bronchospasm, convulsive tendencies and diseases of the liver or kidney.

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

The veterinary medicinal product is intended for external use for eradication of arachnids and insects and must not be taken internally either by animals or humans.

Store away from food and feed.

Do not drink, eat or smoke while using the veterinary medicinal product.

Avoid direct contact of the veterinary medicinal product with the skin and eyes. Phoxim is slightly irritating to the skin and eyes.

People with known hypersensitivity to phoxim should avoid contact with the veterinary medicinal product.

In case of accidental spillage onto skin, wash with water and soap. In case of accidental spillage into the eyes wash with plenty of water.

When using the veterinary medicinal product in closed buildings ensure that the room is well ventilated.

Personal protective equipment consisting of gloves (disposable nitrile safety gloves) and protective clothes (long-sleeved shirt, long pants and boots) should be worn when handling the veterinary medicinal product.

Accidentally contaminated clothes should be removed immediately.

Do not reuse the empty packaging container.

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. As with other organophosphates, in case of toxic symptoms seek medical attention immediately and present the product label.

To the physician:

Poisoning from organophosphorus compounds results from blockage of acetylcholinesterase, which consequence an increase of acetylcholine in the synaptic cleft. 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 veterinary medicinal product is intended to be applied by veterinarians, pest control operators or by informed farmers, who are advised by a veterinarian. The veterinary medicinal product should not be used without wearing protective equipment as specified. 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.

#### Special precautions for the protection of the environment:

The veterinary medicinal product is highly toxic to aquatic organisms, birds and bees.

Phoxim is highly toxic to fish and aquatic invertebrates. When spreading manure from treated animals on agricultural lands a safety distance of 10 m to adjacent surface waters must be kept to avoid exposure of the aquatic environment.

Unused product or waste material should not come into water courses as this may be dangerous for fish and other aquatic organisms. It may cause long-term adverse effects in the aquatic environment.

### **3.6 Adverse events**

Pigs.

Rare (1 to 10 animals / 10 000 animals treated):	Application site irritation Allergic reaction
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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 the national competent authority via the national reporting system. See the immediate packaging for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

#### Pregnancy:

Can be used during all stages of pregnancy.

### 3.8 Interaction with other medicinal products and other forms of interaction

Do not administer other cholinesterase inhibitors, phenothiazines or muscle relaxants from 10 days before to 10 days after application of the veterinary medicinal product. The concurrent use of general anesthetics should also be avoided.

### 3.9 Administration routes and dosage

Pour-on use.

A single dose of 30 mg/kg body weight (b.w.), corresponding to 0.4 ml/kg body weight is recommended, resulting in the following dosage schedule for pigs of different weights:

Weights of pigs (b.w.)	Dose (ml)
10 kg	4 ml
50 kg	20 ml
100 kg	40 ml
150 kg	60 ml

Heavy breeding animals receive correspondingly more.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The veterinary medicinal product is a ready-to-use solution for pouring over the animal's back. The veterinary medicinal product is administered with the original Pour-on Applicator or with an automatic applicator syringe along the mid-line of the back from the ears to the tailhead. In animals with severe ear mange it is recommended to apply 1-2 ml of the dosage volume of the veterinary medicinal product into each ear.

Treatment of lice infestations (*Haematopinus suis*): a single application of 30 mg/kg.

Treatment of sarcoptic mange (*Sarcoptes scabiei* var. *suis*): two applications of 30 mg/kg two weeks apart. The use of a single treatment can lead to disappearance of clinical signs but is generally not sufficient to obtain parasitological cure.

When implementing a programme of mange treatment it is important to treat all animals in a herd. Premises and equipment with which the animals come into direct contact must be sprayed with a suitable disinfectant.

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

Like all organophosphates, inadvertent overdosing can lead to toxic effects such as drooling of saliva, nystagmus, diarrhea, bradycardia, muscle stiffness, ataxia, tremor, convulsions and ultimately coma with respiratory distress.

The therapy consists of symptomatic measures and antidote treatment with atropine (basic dose: from 0.1 mg/kg i.v. or i.m.). The dosage should be adjusted individually depending on the severity of the symptoms. Treatment should continue until salivation stops and should be repeated if symptoms recur.

### **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**

Meat and offal: 17 days.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code : QP53AF01**

### **4.2 Pharmacodynamics**

Phoxim is an inhibitor of the enzyme cholinesterase (AChE) at the nerve ganglia synapses. The inhibition of the enzyme is irreversible under physiological conditions. Postsynaptic accumulation of acetylcholine interferes with normal impulse transmission in the arthropods nervous system. A phase of marked hyperexcitation and convulsion is followed by paralysis and death. Phoxim is active against *Sarcoptes scabiei* var. *suis* and *Haematopinus suis*.

### **4.3 Pharmacokinetics**

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

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

None known.

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

Shelf life after first opening the immediate packaging: 9 months.

### **5.3 Special precautions for storage**

Do not store above 25 °C.

### **5.4 Nature and composition of immediate packaging**

1 l: high-density polyethylene (HDPE) white plastic bottle with light blue polypropylene/polypropylene (PP/PP) screw cap, colorless opaque polypropylene (PP) pour-on doser and colorless opaque high-density polyethylene (HDPE) dip tube. [FR: <in a carton box.>]

5 l: high-density polyethylene (HDPE) white plastic canister with black high-density polyethylene (HDPE) screw cap with high-density polyethylene (HDPE) sealing disc and tamper proof.

Pack sizes:

Bottle with 1L pour-on solution. [FR: <in a carton box.>]

Canister with 5L pour-on solution.

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 aquatic organisms, birds and bees.

The veterinary medicinal product should not enter water courses as phoxim may be dangerous for fish and other aquatic organisms. When spreading manure from treated animals on agricultural lands a safety distance of 10 m to adjacent surface waters must be kept to avoid exposure of the aquatic environment.

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**

Date of first authorisation: DD month YYYY

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

MM/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<sup>1</sup>/IMMEDIATE<sup>2</sup> PACKAGE**

<sup>1</sup> FR: Carton box 11

<sup>2</sup> FR: Fold-out label (without outer carton): 5l canister

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

Sebacil Pour-on 75 mg/ml pour-on solution

**2. STATEMENT OF ACTIVE SUBSTANCES**

Phoxim 75 mg/ml

**3. PACKAGE SIZE**

11

51

**4. TARGET SPECIES**

Pigs

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Pour-on use.

**7. WITHDRAWAL PERIODS**

Withdrawal periods:

Meat and offal: 17 days.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 9 months.

Once opened use by ...

**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**

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**FR: Fold-out label (with outer carton): 1l bottle**

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

Sebacil Pour-on 75 mg/ml pour-on solution

**2. STATEMENT OF ACTIVE SUBSTANCES**

Phoxim 75 mg/ml

1 l

**3. TARGET SPECIES**

Pigs

**4. ROUTES OF ADMINISTRATION**

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

Withdrawal periods:

Meat and offal: 17 days.

**6. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 9 months.

Once opened use by ...

**7. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25 °C.

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

**9. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**DE:** Fold-out label (without outer carton): 1l bottle, 5l canister

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

Sebacil Pour-on 75 mg/ml pour-on solution

**2. STATEMENT OF ACTIVE SUBSTANCES**

Phoxim 75 mg/ml

**3. PACKAGE SIZE**

1 l  
5 l

**4. TARGET SPECIES**

Pigs

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Pour-on use.

**7. WITHDRAWAL PERIODS**

Withdrawal periods:  
Meat and offal: 17 days.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 9 months.  
Once opened use by ...

**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**

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Sebacil Pour-on 75 mg/ml pour-on solution for pigs

### 2. Composition

Each ml contains:

**Active substances:**

Phoxim 75 mg

Blue solution.

### 3. Target species

Pigs.

### 4. Indications for use

For the treatment of mange (*Sarcoptes scabiei* var. *suis*) and lice infestations (*Haematopinus suis*) in pigs.

### 5. Contraindications

Do not use the veterinary medicinal product on sick or highly stressed animals or during convalescence. Do not use in cases of hypersensitivity to organophosphates or to any of the excipients.

### 6. Special warnings

Special precautions for safe use in the target species:

See section "Interaction with other medicinal products and other forms of interaction".

Particular caution is indicated when using the veterinary medicinal product on animals with heart failure, bronchospasm, convulsive tendencies and diseases of the liver or kidney.

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

The veterinary medicinal product is intended for external use for eradication of arachnids and insects and must not be taken internally either by animals or humans.

Store away from food and feed.

Do not drink, eat or smoke while using the veterinary medicinal product.

Avoid direct contact of the veterinary medicinal product with the skin and eyes. Phoxim is slightly irritating to the skin and eyes.

People with known hypersensitivity to phoxim should avoid contact with the veterinary medicinal product.

In case of accidental spillage onto skin, wash with water and soap. In case of accidental spillage into the eyes wash with plenty of water.

When using the veterinary medicinal product in closed buildings ensure that the room is well ventilated.

Personal protective equipment consisting of gloves (disposable nitrile safety gloves) and protective clothes (long-sleeved shirt, long pants and boots) should be worn when handling the veterinary medicinal product.

Accidentally contaminated clothes should be removed immediately.

Do not reuse the empty packaging container.

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. As with other organophosphates, in case of toxic symptoms seek medical attention immediately and present the product label.

To the physician:

Poisoning from organophosphorus compounds results from blockage of acetylcholinesterase, which consequence an increase of acetylcholine in the synaptic cleft. 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 veterinary medicinal product is intended to be applied by veterinarians, pest control operators or by informed farmers, who are advised by a veterinarian. The veterinary medicinal product should not be used without wearing protective equipment as specified. 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.

Special precautions for the protection of the environment:

The veterinary medicinal product is highly toxic to aquatic organisms, birds and bees.

Phoxim is highly toxic to fish and aquatic invertebrates. When spreading manure from treated animals on agricultural lands a safety distance of 10 m to adjacent surface waters must be kept to avoid exposure of the aquatic environment.

Unused product or waste material should not come into water courses as this may be dangerous for fish and other aquatic organisms. It may cause long-term adverse effects in the aquatic environment.

Pregnancy:

Can be used during all stages of pregnancy.

Interaction with other medicinal products and other forms of interaction:

Do not administer other cholinesterase inhibitors, phenothiazines or muscle relaxants from 10 days before to 10 days after application of the veterinary medicinal product. The concurrent use of general anesthetics should also be avoided.

Overdose:

Like all organophosphates, inadvertent overdosing can lead to toxic effects such as drooling of saliva, nystagmus, diarrhea, bradycardia, muscle stiffness, ataxia, tremor, convulsions and ultimately coma with respiratory distress.

The therapy consists of symptomatic measures and antidote treatment with atropine (basic dose: from 0.1 mg/kg i.v. or i.m.). The dosage should be adjusted individually depending on the severity of the symptoms. Treatment should continue until salivation stops and should be repeated if symptoms recur.

## 7. Adverse events

Pigs.

Rare (1 to 10 animals / 10 000 animals treated):	Application site irritation Allergic reaction
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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 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

Pour-on use.

A single dose of 30 mg/kg body weight (b.w.), corresponding to 0.4 ml/kg body weight is recommended, resulting in the following dosage schedule for pigs of different weights:

Weights of pigs (b.w.)	Dose (ml)
10 kg	4 ml
50 kg	20 ml
100 kg	40 ml
150 kg	60 ml

Heavy breeding animals receive correspondingly more.

To ensure a correct dosage, body weight should be determined as accurately as possible.

In animals with severe ear mange it is recommended to apply 1-2 ml of the dosage volume of the veterinary medicinal product into each ear.

Treatment of lice infestations (*Haematopinus suis*): a single application of 30 mg/kg.

Treatment of sarcoptic mange (*Sarcoptes scabiei* var. *suis*): two applications of 30 mg/kg two weeks apart. The use of a single treatment can lead to disappearance of clinical signs but is generally not sufficient to obtain parasitological cure.

When implementing a programme of mange treatment it is important to treat all animals in a herd. Premises and equipment with which the animals come into direct contact must be sprayed with a suitable disinfectant.

## 9. Advice on correct administration

The veterinary medicinal product is a ready-to-use solution for pouring over the animal's back. The veterinary medicinal product is administered with the original Pour-on Applicator or with an automatic applicator syringe along the mid-line of the back from the ears to the tailhead.

## **10. Withdrawal periods**

Meat and offal: 17 days.

## **11. Special storage precautions**

Keep out of the reach and sight 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 or canister after Exp. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: 9 months.

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater or household waste.

Phoxim is highly toxic to aquatic organisms, birds and bees.

The veterinary medicinal product should not enter water courses as phoxim may be dangerous for fish and other aquatic organisms. When spreading manure from treated animals on agricultural lands a safety distance of 10 m to adjacent surface waters must be kept to avoid exposure of the aquatic environment.

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**

[MA number]

Pack sizes:

Bottle with 1L pour-on solution. [FR: <in a carton box.>]

Canister with 5L pour-on solution.

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 Strasse 324, 24106 Kiel, Germany