

Wording of the statements intended for the Fachinformation in the form of the Summary of Product Characteristics for a veterinary medicinal product

1. Name of the veterinary medicinal product:

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

2. Qualitative and quantitative composition:

100 ml solution contains:

Active substance(s):

Phoxim 7.500 g

Other ingredients:

For a full list of excipients, see section 6.1.

3. Pharmaceutical form:

Pour-on solution. Blue solution.

4. Clinical particulars:

4.1 Target species:

Pigs

4.2 Indications for use, specifying the target species:

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

4.3 Contraindications:

Do not use the product on sick or highly stressed animals or during convalescence.

Do not use in the case of known hypersensitivity to organophosphates or to any of the excipients of the product.

4.4 Special warnings for each target species:

None.

4.5 Special precautions for use:

Special precautions for use in animals:

See section 4.8, "Interaction with other medicinal products and other forms of interaction".

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

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

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

Store separately from food and animal feed. Do not eat, drink or smoke during application.

Avoid direct contact between the product and the skin and eyes. Phoxim is a mild skin and eye irritant. People with known hypersensitivity to the active substance should avoid contact with this veterinary medicinal product.

If the product accidentally comes into contact with the skin of the person applying it, it should be washed off immediately with soap and water.

If the product gets accidentally into the eyes, they should be rinsed carefully with plenty of water.

Ensure sufficient ventilation if the product is applied indoors.

During application of the veterinary medicinal product, protective gloves (disposable nitrile gloves) and protective clothing (long-sleeved top, long trousers and rubber boots) must be worn.

Any clothing accidentally contaminated with the product should be changed immediately.

Do not reuse the empty container. Phoxim is an organophosphate. Do not use if you have been advised by a doctor not to work with this class of active ingredients. If you have previously felt unwell after using a different organophosphate-containing product, you should consult a doctor before using this product and show him/her the package leaflet.

As with other organophosphates, consult a doctor immediately if you notice symptoms of poisoning, and show him/her the package leaflet.

Information for the doctor: Organophosphate poisoning is caused by the inhibition of acetylcholinesterase, which leads to an accumulation of acetylcholine in the synaptic cleft. Symptoms include: headache, fatigue, weakness, confusion, blurred vision, heavy perspiration and salivation, cramp-like abdominal pain, a sensation of pressure in the chest, diarrhea, pinpoint pupils and excessive bronchial secretions. These symptoms can occur up to 24 hours after exposure. Cases of severe poisoning can cause generalized muscle twitching, loss of coordination, severe shortness of breath and seizures, which can lead to loss of consciousness without medical treatment. If poisoning is suspected, symptomatic treatment should be given and arrangements made immediately for the patient to be admitted to hospital.

The veterinary medicinal product should be applied only by veterinary surgeons or by pest control experts and informed farmers who have been advised by a veterinary surgeon. The veterinary medicinal product should not be applied without the recommended protective clothing. The person applying the product must follow all the requirements relating to protective clothing and must comply with all protective measures. It is vital to ensure that spare clothes are available in case clothing is damaged.

Other precautionary measures:

Phoxim is highly toxic to aquatic organisms, birds and bees. Phoxim can cause long-term adverse effects in the aquatic environment.

4.6 Adverse reactions (frequency and seriousness):

In rare cases local skin irritation and allergic reactions have been observed, especially around the application site.

Any adverse effects observed after using Sebacil Pour-on should be reported to the Federal Agency for Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Mauerstr. 39-42, 10117 Berlin) or to the marketing authorization holder.

Report forms are available free of charge from the above address or by e-mail (uaw@bvl.bund.de). Veterinary surgeons can submit reports online (form available on the website: <http://vet-uaw.de>).

4.7 Use during pregnancy, lactation or lay:

The product can be used during all stages of pregnancy.

4.8 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 product. The concurrent use of general anesthetics should also be avoided.

4.9 Amounts to be administered and administration route:

Dosage and treatment regimen:

Single dose of 30 mg phoxim/kg body weight. This is equivalent to a dose of 0.4 ml Sebacil Pour-on per 1 kg body weight.

Accordingly, the following doses apply for pigs:

10 kg body weight	4 ml Sebacil Pour-on
50 kg body weight	20 ml Sebacil Pour-on
100 kg body weight	40 ml Sebacil Pour-on
150 kg body weight	60 ml Sebacil Pour-on

Heavy breeding animals receive correspondingly more.

The product is a ready-to-use solution for pouring over the animal's back. The 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 product into each ear.

Treatment of lice infestation (*Haematopinus suis*): a single treatment of 30 mg /kg body weight is sufficient.

Treatment of sarcoptic mange (*Sarcoptes scabiei* var. *suis*): two applications of 30 mg/kg body weight two weeks apart. A single treatment can cause the clinical signs to disappear but is generally not sufficient to achieve a parasitological cure.

In order to eradicate mange, it is important to treat all the animals in a herd, and housing facilities/equipment with which the animals come into direct contact must be sprayed with a suitable pesticide.

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

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.

4.11 Withdrawal period(s):

Pigs:

Edible tissues: 17 days

5. **Pharmacological properties:**

Pharmacotherapeutic group: Ectoparasiticide of the organophosphate group.

ATCvet code: QP53AF01

5.1 Pharmacodynamic properties

Phoxim inhibits the activity of cholinesterase (AChE) at the nerve ganglia.

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.

Phoxim is effective against *Sarcoptes scabiei* var. *suis* and *Haematopinus suis*.

5.2 Pharmacokinetic particulars:

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

5.3 Environmental tolerability

Phoxim is highly toxic to fish and aquatic invertebrates. When spreading slurry from treated animals on agricultural lands a safety distance of 10 m to adjacent surface waters must be maintained because of the risk of run-off.

The veterinary product must not get into water courses after use as it is toxic to fish and other aquatic organisms.

6 **Pharmaceutical particulars:**

6.1 List of excipients:

Paraffin light liquid

2-propanol

Patent blue V, EG no. E 131

1-Butanol

6.2 Incompatibilities:

None known.

6.3 Shelf life:

6.3.1 of the animal health product as packaged for sale:

of the animal health product as packaged for sale: 18 months

Shelf life after first opening the container: 9 months

6.4 Special precautions for storage:

Do not store above 25°C.

6.5 Nature and composition of packaging:

1 l polyethylene bottle, white,
polyethylene screw cap GL 28, light blue
Measuring beaker and dip tube

5 l polyethylene canister, white,
polyethylene screw cap, black

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

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

Contamination of rivers, streams, dams, water reservoirs and other water courses must be avoided, as this poses a danger to fish and aquatic organisms.

When spreading slurry from treated animals on agricultural land, a safety distance of 10 m to adjacent surface waters must be maintained because of the risk of run-off.

Any unused veterinary medicinal products should preferably be deposited at collection centers for hazardous chemicals. If they are disposed of with the household refuse, care should be taken to prevent unauthorized appropriation of such waste material. Veterinary medicinal products must not be disposed of with waste water or via the sewage system.

7. Marketing Authorization holder:

Bayer Vital GmbH
Animal Health Division
51368 Leverkusen

8. Marketing Authorization number:

MA No.: 12201.00.00

9. Date of first authorization / renewal of the authorization:

09.09.1992 / 14.09.2007

10. Date of revision of the text:

October 2017

11. Prohibition of sale, supply and/or use:

Not applicable.

12. Legal category:

Prescription-only