1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maprelin 75 µg/ml solution for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Peforelin 75 µg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Chlorocresol	1.0 mg
Acetic acid, glacial	
Sodium hydroxide	
Water for injections	

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (sows and gilts).

3.2 Indications for use for each target species

For zootechnical use and intended for group or herd treatment.
- Induction of the oestrous cycle in sows after weaning
- Induction of oestrus in sexually mature gilts following therapy to inhibit the oestrus cycle with progestagens

3.3 Contraindications

Do not use in prepubertal gilts, in case of infertility or general health disorders.
Do not use in cases of hypersensitivity to the active substance 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:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product might induce irritation and sensitization.
People with known hypersensitivity to GnRH analogues, such as Peforelin, or any of the excipients should avoid contact with the veterinary medicinal product. The veterinary medicinal product should not be administered by pregnant women, as an accidental self-injection by the user cannot be excluded and because GnRH analogues have been shown to be foetotoxic in laboratory animals. Women of childbearing age should administer the veterinary medicinal product with special caution.
In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
In case of accidental contact with the skin, the corresponding area should be thoroughly cleaned with soap and water, as GnRH analogues may be absorbed through the intact skin. In case of contact with the eyes, they should be thoroughly rinsed with water.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

None.

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

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Laboratory studies in mice produced evidence of teratogenic effects. Do not use during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

The simultaneous treatment of the veterinary medicinal product with PMSG or hCG can possibly lead to an over-reaction of the ovaries.

No interactions were reported following administration of the veterinary medicinal product 48 hours after the end of prior altrenogest therapy.

3.9 Administration routes and dosage

Intramuscular use.
For single application.

Dosage in µg Peforelin and ml of veterinary medicinal product per animal. The dosage is dependent on the parity.

Primiparous sows	24 hours after weaning off the piglets:	37.5 µg = 0.5 ml
Pluriparous sows	24 hours after weaning off the piglets:	150 µg = 2.0 ml
Gilts	48 hours after the termination of the medication for the inhibition of the cycle:	150 µg = 2.0 ml

Use automatic syringe equipment for the 50 ml and 100 ml vials.

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

No adverse reactions were ascertained in pigs following treatment with up to three times the highest recommended dosage.

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

Pigs:
Meat and offal: Zero days.

4. PHARMACOLOGICAL IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QH01CA95

4.2 Pharmacodynamics

Peforelin is a synthetic decapeptide analogue of the Gonadotropin Releasing Hormone (GnRH). The difference to the latter exists with the fact that positions 5 to 8 of the amino acid sequence are exchanged through Histidine, Asparagine, Tryptophan and Lysine. In castrated pigs, Peforelin selectively stimulates the release of FSH. In contrast, the LH secretion is not affected. The secretion of FSH through the single application of Peforelin leads to the growing of the follicles and the induction of oestrus.

4.3 Pharmacokinetics

Following intramuscular treatment Peforelin is rapidly absorbed. The plasma half-life for the GnRH analogues differs depending on the sequence of the molecule and ranges in mammals from a few minutes up to approx. 2 hours. For Peforelin plasma half-life is presumed to be only a few minutes.

The elimination from the bloodstream occurs quickly, whilst the hormonal effect is maintained for several hours.

GnRH analogues only remain in the liver, kidneys and pituitary gland for a very short period. Here they are broken down enzymatically into biologically inactive metabolites, which are then excreted via the renal routes.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store in a refrigerator (2 °C - 8 °C).
Protect from light.
Keep the vial in the outer carton.

5.4 Nature and composition of immediate packaging

Vial of colourless glass, type I, with a fluorinated bromobutyl rubber stopper and an aluminium cap.

Pack sizes:
1 vial (10 ml) in a cardboard box.
6 vials (10 ml) in a cardboard box.
1 vial (50 ml) in a cardboard box.
1 vial (100 ml) in a cardboard box.

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.

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

Veyx-Pharma GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10539/001/001

8. DATE OF FIRST AUTHORISATION

03/07/2009

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

01/06/2026

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).