SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maprelin 75 µg/ml solution for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution for injection contains:

Active substance:

Peforelin 75.00 µg

Excipients:

Chlorocresol 1.00 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (sows and gilts)

4.2 Indications for use, specifying the target species

For biotechnical 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

4.3 Contraindications

Do not use in prepubertal gilts, in case of infertility or general health disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
The product might induce irritation and sensitization.
Persons with a known hypersensitivity to GnRH analogues or any of the excipients should not administer the product. Pregnant women should not administer the product, 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 product with special caution.
In the case of accidental self-injection, seek medical advice and show the package leaflet to the doctor.
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.

4.6 Adverse reactions (frequency and seriousness)

None observed.

4.7 Use during pregnancy, lactation or lay

The safety of the product has not been established in sows and gilts during pregnancy and lactation. Laboratory studies in mice produced evidence of teratogenic effects. Do not use Maprelin in animals during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

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

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

4.9 Amounts to be administered and administration route

Dosage in µg Peforelin and ml Maprelin 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

For intramuscular injection. For single application.
Use automatic syringe equipment for the 50 ml and 100 ml vials.

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

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

4.11 Withdrawal period

Pig:
Meat and offal zero days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Gonadotropin Releasing Hormone-agonist

ATCvet-Code: QH01CA

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Acetic acid, glacial
Sodium hydroxide
Water for injections

6.2 Incompatibilities

None known. Do not mix the product with other medicinal products.

6.3 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.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Veyx-Pharma GmbH
Söhreweg 6
34639 Schwarzenborn
Germany

8. MARKETING AUTHORISATION NUMBER

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9. DATE OF FIRST AUTHORISATION/RENAWAL OF THE AUTHORISATION

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10. DATE OF REVISION OF THE TEXT

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PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.