

For Veterinary Use Only

Pr MAPRELIN XP-10™

Peforelin Injection (as peforelin acetate)
Sterile injectable synthetic gonadotropin releasing hormone
DIN 02465078

Active ingredient: Each mL contains: 75 µg Peforelin (as peforelin acetate)

Preservative: Each mL contains: 1 mg chlorocresol

Therapeutic Classification: Gonadotropin releasing hormone (GnRH) agonist

Indications: For the induction of the estrus cycle in sows after weaning, and in sexually mature gilts following therapy to inhibit the estrus cycle with progestogens.

Dosage and Administration: Dosage is dependent on the parity:

Primiparous sows:

24 hours after weaning off the piglets inject 37.5 µg (0.5 mL) intramuscularly

Pluriparous sows:

24 hours after weaning off the piglets inject 150 µg (2.0 mL) intramuscularly

Gilts:

48 hours after the termination of the medication for inhibition of the estrus cycle inject 150 µg (2.0 mL) intramuscularly

For single intramuscular injection.

Automatic syringe equipment may be used for the 50 mL and 100 mL vial

Contraindications:

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

Cautions:

- 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.
- The simultaneous use of the product with PMSG (*Pregnant Mare Serum Gonadotropin*) or hCG (*Human chorionic gonadotropin*) can possibly lead to an over-reaction of the ovaries.

Warnings:

- No withdrawal period is required for pigs when used according to the label.
- The product might induce irritation and sensitization.
- Persons with a known hypersensitivity to GnRH analogues or any of the excipients should not administer the veterinary medicinal product.
- Pregnant women should not administer the veterinary medicinal product as an accidental self-injection by the user cannot be excluded and because GnRH analogues have been shown to be fetotoxic in laboratory animals.
- Women of childbearing age should exercise special caution when administering this product.
- Special care should be taken to avoid accidental self-injection.
- 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
- Keep out of reach of children.

Clinical Pharmacology:

Pharmacodynamics:

Peforelin is a synthetic decapeptide analogue of the GnRH. The difference to the latter exists with the fact that positions 5 to 8 of the amino acid sequence are exchanged through Histidine, Aspartic acid, 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 estrus.

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 approximately 3 hours. For peforelin plasma half-life is presumed to be within this range. The elimination from the bloodstream occurs quickly, while 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.

Animal Safety:

An animal safety trial was performed in which doses of 1x and 3x the label dose were administered to sexually mature gilts. No adverse events were observed and no reports of abnormal pathology related to the use of the product were noted. The safety of this product after repeat dosing has not been evaluated.

Efficacy:

Gilts: 365 sexually mature gilts were given altrenogest for 18 days at which point they were divided into one of three treatment groups: those receiving no further hormone treatment, those receiving PMSG 48 hours after the final altrenogest therapy, and those receiving 150 µg peforelin 48 hours after the final altrenogest therapy. Gilts treated with peforelin achieved a pregnancy rate of 94.6% and a farrowing rate of 93.9%. The farrowing rate in peforelin treated animals was statistically better than untreated controls ($p < 0.05$), but not statistically better than the farrowing rate in animals treated with PMSG.

Pluriparous sows: 149 sows were injected with 150 µg of peforelin 24 hours after weaning. 93.3% of sows displayed estrus within 6-10 days of injection versus 80.8% in the control group. Inclusion of peforelin 24 hours post weaning improved the weaning to estrus interval ($p < 0.05$). There were no differences between control and treated groups in terms of gestation rates and farrowing rates, litter results from birth to weaning or piglet index.

Primiparous sows: In a preliminary study, it was determined that primiparous sows treated with 150 µg of peforelin 24 hours post weaning did not perform as well as older sows receiving the same amount.

Further studies indicated that a lowered dose (37.5 µg) of peforelin improved the weaning to estrus interval, and the piglet index (based on total piglets born and piglets weaned per litter) compared to untreated animals ($p < 0.05$).

Storage: Store between 2°C-8°C. Do not freeze.

Protect from light. Discard unused product after 28 days of first broaching the vial.

How Supplied: MAPRELIN XP-10 is available in 10, 50 and 100 mL multiple dose vials.

Manufactured for:

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Made in the Netherlands.

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