

## 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 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

#### 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.

People with known hypersensitivity to GnRH analogues 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 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.

#### **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 the product in animals during pregnancy and lactation.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

The simultaneous treatment of the product 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 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

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: QH01CA95

#### **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**

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

Vm 27569/4000

**9. DATE OF FIRST AUTHORISATION**

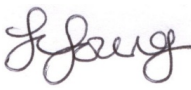
24 June 2009

**10. DATE OF REVISION OF THE TEXT**

March 2014

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

Approved:  04/03/2014